UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

PALM BEACH COUNTY, FL; ALACHUA COUNTY, FL; LEVY COUNTY, FL; OKALOOSA COUNTY, FL; OSCEOLA COUNTY, FL; WALTON COUNTY, FL Plaintiffs, -against- MYLAN PHARMACEUTICALS, INC.; SANDOZ, INC. A/K/A NOVARTIS AG; WEST-WARD PHARMACEUTICALS CORP. N/K/A HIKMA PHARMACEUTICALS, INC.; AMNEAL PHARMACEUTICALS, INC.; AMNEAL PHARMACEUTICALS LLC; KVK-TECH, INC.; INDIVIOR INC. F/K/A RECKITT BENCKISER PHARMACEUTICALS, INC.; ASSERTIO THERAPEUTICS F/K/A DEPOMED, INC.; ZYDUS PHARMACEUTICALS (USA) INC.; ABBOTT LABORATORIES, INC.; SUN PHARMACEUTICAL INDUSTRIES, INC.; COLLEGIUM PHARMACEUTICAL, INC.; KEYSOURCE MEDICAL, INC.; KEYSOURCE ACQUISITION, LLC; QUEST PHARMACEUTICALS, INC.; ASSOCIATED PHARMACIES, INC.; PUBLIX SUPER MARKETS, INC.; SMITH DRUG COMPANY; ALBERTSONS COMPANIES, INC.; ALBERTSON'S LLC; HENRY SCHEIN, INC.; HENRY SCHEIN MEDICAL SYSTEMS, INC.; WINN-DIXIE STORES, INC.; WINN-DIXIE LOGISTICS, INC.; WINN DIXIE LOGISTICS, LLC dba WINN-DIXIE PHARMACY WAREHOUSE #9002; COSTCO WHOLESALE CORPORATION; TARGET CORPORATION; EXPRESS SCRIPTS HOLDING COMPANY; EXPRESS SCRIPTS, INC.; UNITEDHEALTH GROUP INCORPORATED; MEDCO HEALTH SOLUTIONS, INC.; MERCK-MEDCO; OPTUM, INC.; OPTUMRX INC.; NAVITUS	MDL No. 2804 Case No.: **COMPLAINT** **PLAINTIFFS DEMAND A TRIAL BY JURY**

HOLDINGS, LLC; AND NAVITUS HEALTH SOLUTIONS, LLC

Defendants.

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Plaintiffs, Palm Beach County, FL; Alachua County, FL; Levy County, FL; Okaloosa County, FL; Osceola County, FL; and Walton County, FL ("Plaintiffs"), by and through their attorneys, against Defendants Mylan Pharmaceuticals, Inc.; Sandoz, Inc.; Novartis AG; West-Ward Pharmaceuticals Corp. n/k/a Hikma Pharmaceuticals, Inc.; Amneal Pharmaceuticals, Inc.; Amneal Pharmaceuticals LLC ; KVK-Tech, Inc.; Indivior Inc. f/k/a Reckitt Benckiser Pharmaceuticals, Inc.; Assertio Therapeutics f/k/a Depomed, Inc.; Abbott Laboratories, Inc.; Sun Pharmaceutical Industries, Inc.; Collegium Pharmaceutical, Inc.; Zydus Pharmaceuticals (USA) Inc. (Collectively, "Manufacturers," "Manufacturer Defendants," or "Defendants"); KeySource Medical, Inc.; Quest Pharmaceuticals, Inc.; Smith Drug Company; Henry Schein, Inc.; Henry Schein Medical Systems, Inc.; (Collectively, "Distributors," "Distributor Defendants," or "Defendants"); Associated Pharmacies, Inc.; Publix Super Markets, Inc.; Albertsons Companies, Inc.; Albertson's LLC; Winn-Dixie Stores, Inc.; Winn-Dixie Logistics, Inc.; Winn-Dixie Logistics, LLC dba Winn-Dixie Pharmacy Warehouse #9002; Costco Wholesale Corporation; Target Corporation (Collectively, "Distributors," or "Pharmacies," or "Defendants"); Express Scripts Holding Company; Express Scripts, Inc.; UnitedHealth Group Incorporated; Medco Health Solutions, Inc.; Merck-Medco; ; Optum, Inc.; OptumRx Inc.; Navitus Holdings, LLC; Navitus Health Solutions, LLC (collectively, "PBM Defendants" or "Defendants"); (Collectively, "Defendants") alleges as follows:

INTRODUCTION

1. This case is about one thing: corporate greed. Defendants put their desire for profits above the health and well-being of consumers in Plaintiffs' geographic area at the cost of Plaintiffs.

2. Plaintiffs each spend millions of dollars each year to provide and pay for health care, services, pharmaceutical care and other necessary services and programs on behalf of residents who are indigent or otherwise eligible for services, including payments through services

such as Medicaid for prescription opium painkillers ("opioids") which are manufactured, marketed, promoted, sold, distributed, processed, and/or dispensed by the Defendants.

3. Plaintiffs also provide a wide range of other services to their residents, including law enforcement, services for families and children, and public assistance.

4. In recent years, Plaintiffs have been forced to expend exorbitant amounts of money, described further below, due to what is commonly referred to as the "opioid epidemic" and as a direct result of the actions of Defendants.

5. Plaintiffs are also responsible for either partially or fully funding a medical insurance plan for their employees, including the costs of prescription drugs, including opioids.

6. Addiction is a spectrum of substance use disorders that range from misuse and abuse of drugs to addiction.[1] Throughout this Complaint, "addiction" refers to the entire range of substance abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder spectrum.

7. Defendants knew that opioids were effective treatments for short-term post-surgical and trauma-related pain, and for palliative (end-of-life) care. Yet they also knew–and had known for years–that opioids were addictive and subject to abuse, particularly when used long-term for chronic non-cancer pain (pain lasting three months or longer, hereinafter referred to as "chronic pain"), and should there not be used except as a last-resort.

8. Defendants knew that, barring exceptional circumstances, opioids were too addictive and too debilitating for long-term use for chronic non-cancer pain lasting three months or longer.

[1] Diagnostic and Statistical Manual of Mental Disorders (5th ed. 2013) ("DSM-V").

9. Defendants further knew–and had known for years–that with prolonged use, the effectiveness of opioids wanes, requiring increases in doses and markedly increasing the risk of significant side effects and addiction.[2, 3]

10. Defendants also knew that controlled studies of the safety and efficacy of opioids were limited to short-term use (not longer than 90 days), and in managed settings (*e.g.*, hospitals), where the risk of addiction and other adverse outcomes was much less significant.

11. Indeed, the U.S. Food and Drug Administration ("FDA") has expressly recognized that there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.[4]

12. Prescription opioids, which include well-known brand-name drugs like OxyContin and Percocet, and generics like oxycodone and hydrocodone, are narcotics. They are derived from or possess properties similar to opium and heroin, which is why they are regulated as controlled substances.[5] Like heroin, prescription opioids work by binding to receptors on the spinal cord and

[2] *See, e.g.*, Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt. 247 (1994).

[3] The authoritative *Diagnostic and Statistical Manual of Mental Disorders*, (5th ed. 2013) ("DSM-V") classifies addiction as a spectrum of "substance use disorders" that ranges from misuse and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on the substance use disorder continuum. Throughout this Complaint, "addiction" refers to this range of substance use disorders.

[4] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[5] Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. 21 U.S.C. § 812. Schedule II drugs may not be dispensed without an original copy of a manually signed prescription from a doctor, which may not be refilled, and filled by a pharmacist who both must be licensed by their state and registered with the DEA. 21 U.S.C. § 829. Opioids that have been categorized as Schedule II drugs include morphine (Avinza, Embeda, Kadian, MS Contin), fentanyl (Duragesic, Actiq, Fentora), methadone, oxycodone (OxyContin, Percocet, Percodan, Tylox), oxymorphone (Opana), and hydromorphone (Dilaudid, Palladone). Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence. 21 U.S.C. § 812. Schedule III drugs may not be dispensed without a written or oral prescription, which may not be filled or refilled more than six months after the date of the prescription or be refilled more than five times. 21 U.S.C. § 829. Some opioids had been categorized as Schedule III drugs, including forms of hydrocodone and codeine combined with other drugs,

in the brain, dampening the perception of pain. Opioids also can create a euphoric high, which can make them addictive. At certain doses, opioids can slow the user's breathing, causing respiratory depression and death.

13. In order to expand the market for opioids and realize blockbuster profits, Defendants needed to create a sea of change in the medical and public perception that would permit the use of opioids not just for acute and palliative care, but also for long periods of time to treat more common aches and pains, like lower back pain, arthritis, and headaches.

14. Defendants, through a sophisticated and highly deceptive and unfair marketing campaign that began in the late 1990s, deepened around 2006, and continues to the present, set out to, and did, reverse the popular and medical understanding of opioids. Chronic opioid therapy—the prescribing of opioids to treat chronic pain long-term—is now commonplace.

15. To accomplish this reversal, Defendants spent hundreds of millions of dollars: (a) developing and disseminating seemingly truthful scientific and educational materials and advertising that misrepresented the risks, benefits, and superiority of opioids long-term use to treat chronic pain (b) deploying sales representatives who visited doctors and other prescribers and delivered misleading messages about the use of opioids (c) recruiting prescribing physicians as paid speakers as a means to secure those physicians' future "brand loyalty" and extend their reach to all physicians; (d) funding, assisting, encouraging, and directing certain doctors, known as "key opinion leaders" ("KOLs"), not only to deliver scripted talks, but also to draft misleading studies, present continuing medical education programs ("CMEs") that were deceptive and lacked balance, and serve on the boards and committees of professional societies and patient advocacy groups that delivered messages and developed guidelines supporting chronic opioid therapy; and (e) funding,

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like acetaminophen. However, in October 2013, the FDA, following the recommendation of its advisory panel, reclassified all medications that contain hydrocodone from Schedule III to Schedule II. *See* 21 C.F.R. § 1308.

assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups") that developed educational materials and treatment guidelines that were then distributed by Defendants, which urged doctors to prescribe, and patients to use, opioids long-term to treat chronic pain.

16. These efforts, executed, developed, supported, and directed by Defendants, were designed not to present a fair view of how and when opioids could be safely and effectively used, but rather to convince doctors, patients, and others that the benefits of using opioids to treat chronic pain outweighed the risks and that opioids could be used safely by most patients. Defendants and the third parties whom they recruited and supported, all profited handsomely through their dissemination of the deceptive information. KOLs and Front Groups saw their stature in the medical community elevated dramatically due to Defendants' funding, and Defendants saw an equally dramatic rise in their revenues.

17. Working individually, with, and through these Front Groups and KOLs, Defendants pioneered a new and far broader market for their potent and highly addictive drugs— the chronic pain market. Defendants persuaded doctors, patients, and others that what they had long understood—that opioids are addictive drugs and unsafe in most circumstances for long-term use—was untrue, and to the contrary, that the compassionate treatment of pain *required* opioids. Ignoring the limitations and cautions in their own drugs' labels, Defendants: (a) overstated the benefits of chronic opioid therapy, promised improvement in patients' function and quality of life, and failed to disclose the lack of evidence supporting long-term use; (b) trivialized or obscured their serious risks and adverse outcomes, including the risk of addiction, overdose, and death; (c) overstated their superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives; and (d) mischaracterized the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms. There was, and is, no reliable scientific

evidence to support Defendants' marketing claims, and there was, and is, a wealth of scientific evidence that these claims are simply false. Defendants also deceptively and unfairly marketed the drugs for indications and benefits that were outside of the drugs' labels and not supported by substantial evidence.

18. Even Defendants' KOLs initially were very cautious about whether opioids were appropriate to treat chronic pain. Some of these same KOLs have since recanted their pro-opioid marketing messages and acknowledged that Defendants' marketing went too far. Yet despite the voices of renowned pain specialists, researchers, and physicians who have sounded the alarm on the overprescribing of opioids to treat chronic pain, Defendants continue to disseminate their misleading and unfair marketing claims to this day.

19. Defendants' efforts were wildly successful in expanding opioid abuse. The United States is now awash in opioids. In 2012, health care providers wrote 259 million prescriptions for opioid painkillers— enough to medicate every adult in America around the clock for a month. Twenty percent of all doctors' visits in 2010 resulted in the prescription of an opioid, nearly double the rate in 2000. Opioids—once a niche drug—are now the most prescribed class of drugs—more than blood pressure, cholesterol, or anxiety drugs. While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply.

20. Together, opioids generated $8 billion in revenue for drug companies in 2012. Of that amount, $3.1 billion went to Purdue for its OxyContin sales. By 2015, sales of opioids grew further to approximately $9.6 billion.[6]

[6] D. Crow, *Drugmakers hooked on $10bn opioid habit*, Financial Times (August 10, 2016).

21. It was Defendants' marketing—and not any medical breakthrough—that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic.

22. Indeed, the National Institutes of Health "NIH" not only recognizes the opioid abuse problem, but also identifies Defendants' "aggressive marketing" as a major cause: "Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive marketing by pharmaceutical companies*." [7] As shown herein, the "drastic increases in the number of prescriptions written and dispensed" and the "greater social acceptability for using medications for different purposes" are not really independent causative factors but are in fact the direct result of "the aggressive marketing by pharmaceutical companies."

23. According to the U.S. Centers for Disease Control and Prevention ("CDC"), the nation has been swept up in an opioid-induced "public health epidemic."[8] According to the CDC, prescription opioid use contributed to 16,651 overdose deaths nationally in 2010; 16,917 in 2011; and 16,007 in 2012.

24. From 1999 through 2016, more than 350,000 people died from an overdose involving any opioids. Well over half of those deaths—over 200,000 people—involved opioids prescribed by doctors to treat pain. These opioids include brand-name prescription medications like OxyContin, Opana ER, Vicodin, Subsys, and Duragesic, as well as generics like oxycodone, hydrocodone, and fentanyl.

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[7] America's Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2015/americas-addiction-to-opioids-heroin-prescription-drug-abuse#_ftn2 (accessed August 18, 2017) (emphasis added).

[8] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/t20140429.htm (accessed May 30, 2017).

25. Plaintiffs taken steps and will foreseeably continue to take steps in efforts to combat the opioid epidemic which has been caused by the actions of the Defendants. These government efforts create an increased cost and spending.

26. Due to the continued rise of the opioid epidemic and deaths, Plaintiffs have taken steps and will continue to take steps to fight the use of opioids and save lives.

27. The commission of criminal acts to obtain opioids is an inevitable consequence of opioid addiction.

28. But even these alarming statistics do not fully communicate the toll of prescription opioid abuse on patients and their families.

29. The dramatic increase in opioid prescriptions to treat common chronic pain conditions has resulted in a population of addicts who seek drugs from doctors. When turned down by one physician, many of these addicts deploy increasingly desperate tactics—including doctor-shopping, use of aliases, and criminal means—to satisfy their cravings.

30. Efforts by doctors to reverse course for a chronic pain patient already on opioids long-term include managing the physical suffering and psychological distress a patient endures while withdrawing from the drugs. This process is often thwarted by a secondary criminal market well-stocked by a pipeline of drugs that is diverted to supply them. Even though they never would have prescribed opioids in the first place, many doctors feel compelled to continue prescribing opioids to patients who have become dependent on them.

31. According to the CDC, more than 12 million Americans aged 12 or older have used prescription painkillers without a prescription in 2010, and adolescents are abusing opioids in alarming numbers.[9]

[9] CDC, *Prescription Painkiller Overdoses in the US* (Nov. 2011), https://www.cdc.gov/vitalsigns/painkilleroverdoses/ (accessed May 30, 2017).

32. Opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, imposing additional burdens on Plaintiffs and local agencies that address heroin use and addiction. According to the CDC, the percentage of heroin users who also use opioid pain relievers rose from 20.7% in 2002-2004 to 45.2% in 2011-2013. Heroin produces a very similar high to prescription opioids but is often cheaper. While a single opioid pill may cost $10-$15 on the street, users can obtain a bag of heroin, with multiple highs, for the same price. It is hard to imagine the powerful pull that would cause a law-abiding, middle-aged person who started on prescription opioids for a back injury to turn to buying, snorting, or injecting heroin, but that is the dark side of opioid abuse and addiction.

33. Dr. Robert DuPont, former director of the National Institute on Drug Abuse, opines that opioids are more destructive than crack cocaine:

> [Opioid abuse] is building more slowly, but it's much larger. And the potential for death, in particular, [is] way beyond anything we saw then. . . . [F]or pain medicine, a one-day dose can be sold on the black market for $100. And a single dose can [be] lethal to a non-patient. There is no other medicine that has those characteristics. And if you think about that combination and the millions of people who are using these medicines, you get some idea of the exposure of the society to the prescription drug problem.[10]

34. Countless Plaintiff residents suffer from chronic pain, which takes an enormous toll on their health, their lives, and their families. These residents deserve both appropriate care and the ability to make decisions based on accurate and complete information about treatment risks and benefits. But Defendants' deceptive and unfair marketing practices deprived County residents and

[10] Transcript, *Use and Abuse of Prescription Painkillers*, The Diane Rehm Show (Apr. 21, 2011), http://thedianerehmshow.org/shows/2011-04-21/use-and-abuse-prescription-painkillers/transcript (accessed May 30, 2017).

their doctors of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype. Defendants deprived patients, their doctors, and health care payors of the chance to exercise informed judgment and subjected them to enormous costs and suffering.

35. Defendants' actions are not permitted or excused by the fact that their labels may have allowed, or did not exclude, the use of opioids for chronic non-cancer pain. The FDA's approval did not give Defendants license to misrepresent the risks, benefits, or superiority of opioids. Indeed, what makes Defendants' efforts particularly nefarious—and dangerous—is that, unlike other prescription drugs marketed unlawfully in the past, opioids are highly addictive controlled substances. Defendants deceptively and unfairly engaged a patient base that—physically and psychologically—could not turn away from their drugs, many of whom were not helped by the drugs or were profoundly damaged by them.

36. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were both ubiquitous and highly persuasive; their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants targeted not only pain specialists, but also primary care physicians (PCPs), nurse practitioners, physician assistants, and other non-pain specialists who were even less likely to be able to assess the companies' misleading statements. Defendants were also able to callously manipulate what doctors wanted to believe—namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

37. By 2014, nearly two million Americans were either abusing opioid medications or were dependent on opioids.[11] According to the CDC, opioids have created a "public health epidemic" as of 2016.[12]

38. Defendants' marketing campaign has been extremely harmful and has cost American lives – including lives of residents of Plaintiffs. Deaths from prescription opioids have quadrupled since 1999. From 2000 to 2014 nearly 500,000 people died from such overdoses; seventy-eight Americans die every day from opioid overdoses.[13]

39. It is estimated that, in 2012, 2.1 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers.[14]

40. The rising numbers of persons addicted to opioids have led not only to an increase in health care costs to Plaintiffs, but also a major increase in issues such as drug abuse, diversion,[15] and crimes related to obtaining opioid medications. Plaintiffs have been severely and negatively impacted due to the fraudulent misrepresentations and omissions by Defendants regarding the use and risk related to opioids. In fact, upon information and belief, Defendants have been and continue to be aware of the high levels of diversion of their product.

41. The actions of Defendants have created an environment where select physicians have sought to profit at the expense of their patients who become addicted to opioid pain medications, often accepting cash payments and ordering unnecessary medical tests, again at the expense of Plaintiffs.

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[11] CDC, Injury Prevention & Control: Opioid Overdose, Prescription Opioids, Addiction and Overdose. Available at http://www.cdc.gov/drugoverdose/opioids/prescribed.html (accessed May 30, 2017).
[12] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse*, (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/ts0140429.htm (accessed May 30, 2017).
[13] CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic.
[14] Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H- 46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.
[15] The CDC defines using or obtaining opioids illegally as "diversion."

42. Prescription drug manufacturers, wholesalers/distributors, pharmacies, and pharmacy benefit managers ("PBMs") have created this epidemic. The manufacturers make the opioids and lie about their efficacy and addictive properties. The wholesalers distribute the opioids from the point of manufacture to the point of delivery to the patient. The pharmacies distribute and dispense opioids. And the PBMs control, through their formularies, which drugs go where and how they are paid for.

43. PBMs are a necessary party to any discussion of opioid-related misconduct committed by pharmaceutical supply chain actors, and its ramifications. Neither courts nor the governmental entities left to clean up the opioid crisis can address the flow of opioids or the costs of abatement without including the parties that are in fact capable of controlling that flow, across all manufacturers and distributors, i.e. the PBMs.

44. PBMs are the gatekeepers to the vast majority of opioid prescriptions filled in the United States. Caremark, Express Scripts, and OptumRx (all named defendants here) manage the drug benefits for approximately ninety-five percent (95%) of the United States' population or 253 million American lives.[16] PBMs control drug formularies which set the criteria and terms under which pharmaceutical drugs are reimbursed. In this way, PBMs control prescription drug utilization overall.

45. PBMs' complicity in the overall fraudulent scheme is purposeful given the nature of the financial arrangements between PBMs and drug manufacturers and others in the supply chain. Drug manufacturers compete for PBM formulary placement (preferred placement results in greater utilization and greater profits) and pay PBMs incentives to avoid pre-authorization requirements that would slow down flow.

[16] Brittany Hoffman-Eubanks, The Role of Pharmacy Benefit Managers in American Health Care: Pharmacy Concerns and Perspectives: Part 1, PHARMACY TIMES, Nov. 14, 2017, http://www.pharmacytimes.com/news/the-role-ofpharmacy-benefit-mangers-in-american-health-care-pharmacy-concerns-and-perspectives-part-1

46. PBMs require, and receive, incentives from Manufacturer Defendants to keep certain drugs on and off formularies. These incentives include the payment of rebates by Manufacturers Defendants to PBMs based on utilization, bonuses for moving product and hitting volume targets, and the payment of lucrative administrative fees to maximize PBM profits. Much of this activity is not transparent to anyone, including those who in good faith hire PBMs to manage their benefits.

47. PBMs are the middlemen between the manufacture and the availability of opioids. The PBM formularies determine what drugs (a) will be available (or not available) to patients; (b) for what diagnosis, efficacious or otherwise; (c) in what quantities; (d) at what co-pay; (e) what level of authorization will be required; and (f) what beneficial drugs will not be available. PBMs collude with Manufacturers who pay fees in the form of rebates, administrative fees and other, in order to ensure good placement on the formulary to the financial benefit of the PBMs. This leads to more prescriptions and more pills available to the general public, many of which find their way to the black market. PBMs have in their exclusive power the ability to limit the number of pills available for legitimate and illegitimate consumption. Even though PBMs were well aware of the effect of their decisions about formulary placement, they chose to make decisions purely for their own financial gain.

48. PBMs not only control the majority of this country's prescriptions through their formularies, they generate massive profits from that work. "[N]early one third of all expenditures on branded drugs in 2015 were eventually rebated back. And, most of these rebates directly benefited the PBM."[17]

[17] Wayne Winegarden, To Improve Pharmaceutical Pricing, Reform PBMs And Fix Health Care's Systemic Problems, FORBES, Apr. 4, 2017, https://www.forbes.com/sites/econostats/2017/04/04/to-improve-pharmaceutical-pricingreform-pbms-and-fix-health-cares-systemic-problems/#4da58c5a3322

49. PBMs can extract rebates and other incentives from Manufacturer Defendants because of the PBMs' market power. Today, PBMs have leveraged their position as the middlemen and now impact almost every aspect of the prescription drug marketplace.

50. "The position of the three major PBMs at the center of the drug distribution system appears to be unassailable for now. Last year CalPERS, California's public employee benefits system, awarded OptumRx a five-year, $4.9-billion contract to manage prescriptions for nearly 500,000 members and their families enrolled in non-HMO health plans. The only other finalists in the bidding were CVS Caremark and Express Scripts,"[18] all defendants here.

51. The power of the PBMs has evolved over time. Originally mere claims processors, PBMs now play a major role in managing pharmaceutical spending and enhancing health benefits for end-users. [19]

52. PBMs quietly became an integral part of the pharmaceutical supply chain—that is, the path a drug takes from the manufacturing facility to a bathroom medicine cabinet—following the passage of the Medicare Modernization Act in 2003.[20]

53. Because PBMs are the intermediary between drug manufacturers, pharmacies, and ultimately patients, these companies control everything from pharmacy reimbursements to what drugs are covered under formularies.[21] In these ways, the PBMs control which drugs enter the marketplace. Their fingerprints are on nearly every opioid prescription filled and they profit in myriad ways on every pill.

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[18] Michael Hiltzik, How 'price cutting' middlemen are making crucial drugs vastly more expensive, LOS ANGELES TIMES, Jun. 9, 2017, http://www.latimes.com/business/hiltzik/la-fi-hiltzik-pbm-drugs-20170611-story.html

[19] Zacks Equity Research, PBM Industry Shows Strength: 3 Stocks in Focus, NASDAQ, Dec. 13, 2017, http://www.nasdaq.com/article/pbm-industry-shows-strength-3-stocks-in-focus-cm891506

[20] Jessica Wapner, Understanding the Hidden Villain of Big Pharma: Pharmacy Benefit Managers, NEWSWEEK, Mar. 17. 2017, http://www.newsweek.com/big-pharma-villain-pbm-569980

[21] Matthew Kandrach, PBM stranglehold on prescription drug market demands reform, THE HILL, May 2, 2017, http://thehill.com/blogs/pundits-blog/healthcare/331601-pbm-stranglehold-on-prescription-drug-market-demandsreform

54. The harm caused by the PBMs is not just monetary: "[t]he PBMs and insurers are harming the health of patients with chronic and rare diseases by limiting access and charging them retail for drugs they buy at deep discounts."[22]

55. MedPageToday, a source for clinical and policy coverage that directly affects the lives and practices of health care professionals, describes the PBMs' complicity in the opioid crisis this way:

> If you are looking for someone to blame for the opioid epidemic, you can certainly blame physicians. You can blame pharmaceutical companies. But while you are at it, don't forget to include payers [PBMs]. This conclusion should not be surprising. We live in a world where payers -- not physicians -- determine what drugs and treatments patients receive. If patients have a life-threatening condition, it is not unusual for a payer to demand that a physician first prescribe a cheaper and less effective alternative. Physicians know that the drugs they are allowed to use may not work very well, but frequently, payers demand that they be tried first anyway.
>
> What happens if the patient doesn't respond to the cheap drug? Often, the physician continues to prescribe it, because -- to gain access to the more effective drug -- physicians need to go through a painful process of preauthorization. For many practitioners, it isn't worth it.
> So we spend more for healthcare than any other country in the world, but Americans do not get the care they need. There is a simple reason. Treatment decisions are not being driven based on a physician's knowledge or judgment. They are being driven by what payers are willing to pay for.[23]

56. As one news outlet described it, "[o]ne overlooked culprit worsening the epidemic, however, comes straight from our health care system: pharmacy benefit managers, or PBMs. To

[22] Jonathan Wilcox, PBMs Must Put Patients First, HUFFINGTON POST, Feb. 28, 2017, https://www.huffingtonpost.com/entry/pbms-must-put-patients-first_us_58b60bd8e4b02f3f81e44dcc

[23] Milton Packer MD, Are Payers the Leading Cause of Death in the United States?, MEDPAGETODAY, Nov. 1, 2017, https://www.medpagetoday.com/blogs/revolutionandrevelation/68935

improve their bottom line, they're blocking access to prescriptions that can help prevent overdoses."[24]

57. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiffs have each been required to spend millions of dollars each year in its efforts to combat the public nuisance created by Defendants' deceptive marketing campaign. Plaintiffs have incurred and continue to incur costs related to opioid addiction and abuse, including, but not limited to, health care costs, criminal justice and victimization costs, social costs, and lost productivity costs. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiffs and their residents.

58. Defendants have not changed their ways or corrected their past misconduct but instead are continuing to fuel the crisis and perpetuate the public nuisance.

59. Plaintiffs bring this suit to bring the devastating march of this epidemic to a halt and to hold Defendants responsible for the crisis they caused.

JURISDICTION AND VENUE

60. This Court has subject-matter jurisdiction of this action pursuant to 28 U.S.C. § 1331 because the Plaintiffs' claims involve Defendants' duties under federal law, including the Controlled Substance Act.

61. This Court has jurisdiction over Defendants in that Defendants, individually or acting by and through their authorized agents, officers, representatives, servants and employees, operated, conducted, engaged in or carried on a business venture in Florida; maintained an office or agency in this state; solicited business or provided service activities within this state; engaged in

[24] Peter J. Pitts, Pharmacy benefit managers are driving the opioid epidemic, SW NEWS MEDIA, Nov. 21, 2017, http://www.swnewsmedia.com/shakopee_valley_news/news/opinion/guest_columns/pharmacy-benefit-managersare-driving-the-opioid-epidemic/article_2f6be2a1-c7a3-5f8d-9f3e-, 61d29d25c84b.html

substantial and not isolated activity within this state; and/or committed a tortious act within the state by, among other things:

a. Manufacturing, selling and distributing highly addictive prescription opioid drugs in Florida while engaging in a pattern and practice of disseminating patently false and misleading information about the safety and efficacy of these opioid drugs;

b. Intentionally diminishing the associated health hazards of prescription opioid drugs and conspiring with key opinion leaders to increase their sales and profits despite the known risks and dangerous propensity of these drugs;

c. Consensually submitting to the jurisdiction of Florida when obtaining a manufacturer or distributor license; and/or

d. Owning and/or operating a distribution center in Florida that distributes the Defendant manufacturers' prescription opioid drugs to the citizens of Palm Beach County, Florida.

62. Defendants derived substantial revenue as the result of the opioids which were distributed to Florida physicians, patients, and others and later consumed by persons then residing in Florida. Defendants' intentional and tortious conduct is continuing and presently existing, arose out of or is incidental to each Defendant's interstate, intrastate and international business ventures conducted in the United States, including Florida, and proximately caused the Plaintiff to sustain losses and damages in the State of Florida. Accordingly, the Defendants have the requisite minimum contacts with Florida necessary to constitutionally permit this Court to exercise jurisdiction because:

a. The Defendants' contacts with Florida, including, but not limited to, their manufacture, sale, distribution and/or promotion of highly addictive

prescription opioid drugs, are directly related to and gave rise to this Complaint;

b. Defendants' purposefully availed themselves of the privilege of conducting business in the State of Florida by selling, distributing and/or promoting the use of highly addictive prescription opioid drugs to doctors, hospitals, patients, health insurers and other individuals throughout the State of Florida, including, but not limited to, Palm Beach County, Florida; and

c. Defendants' fraudulent and deceptive marketing campaign and intentional misconduct was such that the Defendants should have reasonably anticipated being hauled into court in Florida. See § 48.913, Fla. Stat.

63. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(2) in that a substantial part of the events or omissions giving rise to the claim occurred in the Southern District of Florida. Venue is also proper under 18 U.S.C. § 1965(a) because the Defendants, are found, have agents, or transact their affairs in this district.

PARTIES

A. Plaintiffs.

64. Plaintiff Alachua County is a County within the State of Florida, with a population of approximately 279,238 residents.

65. Plaintiff Levy County is a County within the State of Florida, with a population of approximately 44,158 residents.

66. Plaintiff Okaloosa County is a County within the State of Florida, with a population of approximately 213,255 residents.

67. Plaintiff Osceola County is a County within the State of Florida, with a population of approximately 403,282 residents.

68. Plaintiff Palm Beach County is a County within the State of Florida, with a population of approximately 1.498 million residents.

69. Plaintiff Walton County is a County within the State of Florida, with a population of approximately 80,069 residents.

70. Plaintiffs provide a wide range of services on behalf of their residents, including services for families and children, public health, public assistance, law enforcement, and emergency care.

B. Defendants.[25]

1. Mylan

71. Defendant Mylan Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business located in Canonsburg, Pennsylvania. It manufactures, promotes, markets, distributes and sells opioids in Plaintiffs' geographical area and throughout the nation. This includes many Schedule II controlled substances such as Oxycodone and Propoxy-N. Mylan conducts its pharmaceutical business operations through various entities, including Mylan Specialty, L.P. and Mylan Pharms, Inc. (collectively "Mylan".) At all relevant times, Mylan manufactured, marketed, and sold generic opioids, including fentanyl and oxycodone products, throughout the United States and Plaintiffs' geographic area. Mylan manufactured, marketed, and sold opioids throughout Plaintiffs' geographic area, in violation of the duties owed to Plaintiffs in sufficient quantities to be a proximate cause of Plaintiffs' injuries.

72. As a generic manufacturer, Mylan failed to effectively and adequately communicate warnings in the labels of their products to prescribers and users. Mylan could have communicated

[25] Plaintiffs have made its best efforts, based on the information available, to identify all of the corporate entities with responsibilities related to the sale and distribution of opioids in or affecting Plaintiffs. If information that becomes available to Plaintiffs alters its understanding or discloses additional entities, Plaintiffs reserve the right to seek to join any such entities as defendants. Furthermore, the Counties recognize that corporate entities affiliated with the Defendants may possess discoverable information relevant to Plaintiffs' claims, even though those entities have not been named as defendants. Plaintiffs reserve the right to seek all information relevant to these claims.

the risks associated with the use of prescription opioid drugs through dear doctor or healthcare provider letters. However, Mylan had a financial incentive not to communicate these warning and risks and aggressively marketed its generic opioid products to drug distributors, prescription benefit managers, formularies, insurance companies, and other third parties to increase its own generic market share. Moreover, in the manufacture and sale of its opioid products, Mylan failed to report suspicious orders in violation of its duties under the Controlled Substances Act and local law and knowingly allowed widespread diversion to occur. See 21 C.F.R. § 1301.71(a).

2. Sandoz

73. Defendant Sandoz, Inc. is a Colorado corporation with its principal place of business located in Princeton, New Jersey. Sandoz, Inc. is a subsidiary of Defendant Novartis AG.

74. Sandoz manufactures, promotes, markets, distributes and sells opioids in Plaintiffs' geographical area and throughout the nation. At all times relevant, Sandoz, Inc. manufactured, marketed, and sold opioids, including fentanyl and oxycodone products, throughout the United States and Plaintiffs' geographic area. Sandoz manufactured, marketed, and sold opioids throughout Plaintiffs' geographic area, in violation of the duties owed to Plaintiffs in sufficient quantities to be a proximate cause of Plaintiffs' injuries.

75. As a generic manufacturer, Sandoz failed to effectively and adequately communicate warnings in the labels of their products to prescribers and users. Sandoz could have communicated the risks associated with the use of prescription opioid drugs through dear doctor or healthcare provider letters. However, Sandoz had a financial incentive not to communicate these warning and risks and aggressively marketed its generic opioid products to drug distributors, prescription benefit managers, formularies, insurance companies, and other third parties to increase its own generic market share. Moreover, in the manufacture and sale of its opioid products, Sandoz

failed to report suspicious orders in violation of its duties under the Controlled Substances Act and local law and knowingly allowed widespread diversion to occur. See 21 C.F.R. § 1301.71(a).

3. Novartis

76. Defendant Novartis AG a/k/a Novartis Inc. and Novartis Pharmaceuticals Corporation (collectively "Novartis") is a Delaware corporation and is located at One Health Plaza, East Hanover, New Jersey, 07936-1080 with a registered agent in Florida at Corporation Service Company, 1201 Hays Street, Tallahassee, Florida, 32301.

77. Novartis manufactures, promotes, markets, distributes and sells opioids in Plaintiffs' geographical area and throughout the nation. At all times relevant, Novartis manufactured, marketed, and sold opioids, including fentanyl and oxycodone products, throughout the United States and Plaintiffs' geographic area. Novartis manufactured, marketed, and sold opioids throughout Plaintiffs' geographic area, in violation of the duties owed to Plaintiffs in sufficient quantities to be a proximate cause of Plaintiffs' injuries.

78. As a generic manufacturer, Novartis failed to effectively and adequately communicate warnings in the labels of their products to prescribers and users Novartis could have communicated the risks associated with the use of prescription opioid drugs through dear doctor or healthcare provider letters. However, Novartis had a financial incentive not to communicate these warning and risks and aggressively marketed its generic opioid products to drug distributors, prescription benefit managers, formularies, insurance companies, and other third parties to increase its own generic market share. Moreover, in the manufacture and sale of its opioid products, Novartis failed to report suspicious orders in violation of its duties under the Controlled Substances Act and local law and knowingly allowed widespread diversion to occur. See 21 C.F.R. § 1301.71(a).

4. West-Ward n/k/a Hikma Pharmaceuticals

79. Defendant West-Ward Pharmaceuticals Corp. n/k/a Hikma Pharmaceuticals, Inc. ("Hikma") is a Delaware corporation with its principal place of business located in Eatontown, New Jersey. It manufactures, promotes, markets, distributes and sells opioids in Plaintiffs' geographical area and throughout the nation. At all times relevant, Hikma manufactured, marketed, and sold opioids, including hydromorphone, oxymorphone, and methadone products, throughout the United States and Plaintiffs' geographic area. Hikma manufactured, marketed, and sold opioids throughout Plaintiffs' geographic area, in violation of the duties owed to Plaintiffs in sufficient quantities to be a proximate cause of Plaintiffs' injuries.

80. As a generic manufacturer, Hikma failed to effectively and adequately communicate warnings in the labels of their products to prescribers and users. Hikma could have communicated the risks associated with the use of prescription opioid drugs through dear doctor or healthcare provider letters. However, Hikma had a financial incentive not to communicate these warning and risks and aggressively marketed its generic opioid products to drug distributors, prescription benefit managers, formularies, insurance companies, and other third parties to increase its own generic market share. Moreover, in the manufacture and sale of its opioid products, Hikma failed to report suspicious orders in violation of its duties under the Controlled Substances Act and local law and knowingly allowed widespread diversion to occur. See 21 C.F.R. § 1301.71(a).

5. Amneal

81. Defendant Amneal Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business located in New Jersey. Upon information and belief, Amneal Pharmaceuticals, Inc. is a subsidiary of Amneal Pharmaceuticals LLC.

82. Defendant Amneal Pharmaceuticals, LLC is a foreign limited liability company organized under the laws of Delaware with its principal place of business in Bridgewater, New Jersey, and has a registered agent in Plantation, Florida.

83. Defendant Amneal Pharmaceuticals, Inc. and Defendant Amneal Pharmaceuticals, LLC are collectively referred to as "Amneal".

84. Amneal manufactures, promotes, markets, distributes and sells opioids in Plaintiffs' geographical area and throughout the nation.

85. At all times relevant, Amneal manufactured, marketed, and sold opioids, including generic oxycodone and hydrocodone, throughout the United States and Plaintiffs' geographic area. Amneal manufactured, marketed, and sold opioids throughout Plaintiffs' geographic area, in violation of the duties owed to Plaintiffs in sufficient quantities to be a proximate cause of Plaintiffs' injuries.

86. As a generic manufacturer, Amneal failed to effectively and adequately communicate warnings in the labels of their products to prescribers and users. Amneal could have communicated the risks associated with the use of prescription opioid drugs through dear doctor or healthcare provider letters. However, Amneal had a financial incentive not to communicate these warning and risks and aggressively marketed its generic opioid products to drug distributors, prescription benefit managers, formularies, insurance companies, and other third parties to increase its own generic market share. Moreover, in the manufacture and sale of its opioid products, Amneal failed to report suspicious orders in violation of its duties under the Controlled Substances Act and local law and knowingly allowed widespread diversion to occur. See 21 C.F.R. § 1301.71(a).

6. KVK-Tech

87. Defendant KVK-Tech, Inc. is a privately held Pennsylvania corporation with its principal place of business in Pennsylvania. KVK-Tech, Inc. is a manufacturer of generic

prescription opioids, including many Schedule II controlled substances such as Oxycodone and Hydrocodone. KVK-Tech, Inc. manufactures, markets, sells and/or distributes pharmaceutical drugs nationally and in Plaintiffs' geographic area. KVK-Tech, Inc. is registered to conduct business and/or conducts business in Plaintiffs' geographic areas as a licensed wholesale pharmaceutical manufacturer.

7. Indivior

88. Defendant Indivior Inc. f/k/a Reckitt Benckiser Pharmaceuticals, Inc. ("Indivior") is a Delaware corporation with its principal place of business located at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia 23235.

89. At all times relevant to this Complaint, Indivior Inc. manufactured, marketed, sold, and distributed prescription opioids nationally, including in Plaintiffs' geographic area, including many opioid medications such as Sublocade (buprenorphine), Subutex tablet (buprenorphine), Suboxone tablet (buprenorphine/naloxone), and Suboxone film (buprenorphine/naloxone).

90. In April 2019, the U.S. Department of Justice announced that Indivior Inc. was indicted for fraudulently marketing their Suboxone film opioid as safer, less divertible, and less abusable than other opioid-addiction treatment drugs. Indivior was alleged to have sought to boost profits by using a "Here to Help" program to connect opioid-addicted patients to doctors the company knew were prescribing opioids at high rates and in a clinically unwarranted manner.

91. According to the indictment, Indivior promoted the film version of Suboxone (Suboxone film) to physicians, pharmacists, Medicaid administrators, and others across the country as less-divertible and less-abusable and safer around children, families, and communities that other buprenorphine drugs, even though such claims have never been established.

92. The indictment also alleges that, to further its scheme, Indivior announced a "discontinuance" of its tablet form of Suboxone based on supposed "concerns regarding pediatric

exposure" to tablets, despite Indivior executives' knowledge that the primary reason for the discontinuance was to delay the Food and Drug Administration's approval of generic tablet forms of the drug.

93. In July 2019, the U.S. Department of Justice and Indivior negotiated a $1.4 billion settlement of the issues presented by the indictment.

94. Indivior Solutions, a subsidiary of Indivior Inc., was sentenced to pay $289 million in criminal penalties in connection with a previous guilty plea related to the marketing of the opioid-addiction treatment drug Suboxone. Together with Indivior's civil penalties, it will pay $600 million to resolve its civil and criminal liability.

95. Altogether, the investigation and prosecution of Indivior Solutions and its parent companies, Indivior Inc. and Indivior plc, and two former Indivior executives (its CEO and Medical Director) and a resolution with Indivior's former parent, Reckitt Benckiser Group plc, resulted in recoveries of more than $2 billion.

96. Indivior Solutions pleaded guilty on July 24, 2020, to a one-count felony criminal information charging false statements relating to health care matters. Indivior Inc. agreed to terms complementing the Indivior Solutions guilty plea and agreed to implement prospective measures that include permanently disbanding Indivior Inc.'s Suboxone sales force and taking steps to prevent promoting Suboxone to health care providers at a high risk of inappropriate prescribing.

8. Assertio

97. Defendant Assertio Therapeutics, Inc. f/k/a Depomed, Inc. ("Assertio" or "Depomed") is a Delaware corporation with its principal place of business in Lake Forrest, Illinois. Depomed acquired Nucynta (tapentadol immediate-release oral tablets) and Nucynta ER (tapentadol extended-release tablets) from J&J in April of 2015 and began to manufacture, market,

sell and distribute Nucynta® in the U.S., including in Plaintiffs' geographic areas. Depomed also manufactures, markets, sells, and distributes Lazanda (fentanyl).

98. On information and belief, Depomed entered a Commercialization Agreement with Collegium Pharmaceutical, Inc. (Collegium) in January of 2018 that granted Collegium the right to commercialize Nucynta and Nucynta ER in the U.S. Collegium assumed all commercialization responsibilities for Nucynta effective January 9, 2018, including sales and marketing. Pursuant to the Commercialization Agreement, Depomed will receive a royalty on all Nucynta and Nucynta ER revenues based on certain net sales thresholds, with a minimum royalty of $135 million per year during the first four years of the agreement. Additionally, Depomed retained certain rights to co-promote Nucynta products.

99. Depomed actively promoted and continues to promote the sale and use of its opioid products throughout the U.S., including Plaintiffs' geographic areas. In 2015, Depomed paid over $2.11 million to physicians and hospitals across the U.S. to promote widespread prescribing, sales, and use of Nucynta and Nucynta ER. On information and belief, from 2013 through 2015, Depomed paid $1.07 million to physicians and hospitals across the U.S., including in Plaintiffs' geographic areas, to the promote the sale and use of Lazanda. Additionally, from 2012 to 2017, Depomed paid $1,071,000 to non-profit patient advocacy groups and medical societies to promote opioid prescribing and enhance the acceptance of opioids for non-cancer pain. Specifically, Depomed made payments to several industry front groups, including the Academy of Integrative Pain Management ($43,491.95), American Academy of Pain Medicine ($332,100.00), AAPM Foundation ($304,605.00), American Chronic Pain Association ($54,670.00), American Pain Society ($288,750.00), American Society of Pain Management Nursing ($25,500.00), and U.S. Pain Foundation ($22,000.00).

100. Depomed established a training module called the "Depomed Pain Medicine Education Program" with the American Academy of Pain Medicine, which can be found at the American Academy of Pain Medicine (AAPM) Education Center. The training module appears on the AAPM webpage and "was designed to further sales specialists' knowledge of the fundamentals of pain medicine and gain confidence and credibility when interacting with health care clinicians." The Pain Medicine Education Program promotes use of opioids for chronic pain in older adults and has modules entitled: "Strategies for Success with Chronic Opioid Therapy," "Pain Management with Older Adults," and "Pain and Pathways: Understanding Chronic Low Back Pain."

9. Abbott

101. Abbott Laboratories, Inc. is a domestic BCA organized under the laws of Illinois. Abbott Laboratories is an Illinois corporation with its principal place of business in Abbott Park, Illinois, and Abbott Laboratories, Inc. is an Illinois corporation with its principal place of business in Abbott Park, Illinois (collectively, "Abbott").

102. Abbott was primarily engaged in the promotion, and distribution of opioids nationally, including Plaintiffs' geographic area, due to a co-promotional agreement with Defendant Purdue. Pursuant to that agreement between 1996 and 2006, Abbott actively promoted, marketed, and distributed Purdue's opioid products.

103. With Abbott's help, sales of OxyContin went from a mere $49 million in its first full year on the market to $1.6 billion in 2002. Over the life of the co-promotional agreement, Purdue paid Abbott nearly half a billion dollars.

104. Abbott, as part of the co-promotional agreement, helped make OxyContin into the largest-selling opioid in the nation. Under the co-promotional agreement with Purdue, the more Abbott generated in sales, the higher the reward. Specifically, Abbott received 25 to 30 percent of all net sales for prescriptions written by doctors its sales force called on. This agreement was in

operation from 1996 to 2002, following which Abbott continued to receive a residual payment of 6 percent of net sales up through at least 2006.

105. Abbott heavily incentivized its sales staff to push OxyContin, offering $20,000 cash prizes and luxury vacations to top performers. The company used Middle Age Crusade terminology: Sales reps were called "Crusaders" in the "Royal Court of OxyContin," executives referred to in memos as the "Wizard of OxyContin", "Supreme Sovereign of Pain Management" and the "Empress of Analgesia". The head of pain care sales, Jerry Eichorn, was the "King of Pain" and signed memos simply "King."

106. In one particular memo to Sales Reps, two Abbott Reps received high accolades from "The Kingdom of Abbott Pain Management" for a "particularly outstanding Crusader success story."

107. In this same memo, the "Empress of Analgesia" pushed Sales Reps to hone their focus on 50 key surgeons and anesthesiologists, more specifically to "target those who have the potential to widely prescribe OxyContin and Vicoprofen on a consistent basis each month." The "King of Pain" encouraged sales representatives to use emotion in their sales tactics, and then supplied examples, both based on vague science:

> Did Doctor X have disruptive callbacks from Patient Y today, unhappy with his breakthrough pain levels on Percocet? Explain how OxyContin smooth, sustained blood level throughout 12 hours should alleviate this problem by keeping patients comfortable. Is Surgeon A concerned about the euphoria Patient B is experiencing from Vicodin? Tell your doctor that, with its longer half life, OxyContin has fewer such effects.

108. Abbott and Purdue sales representatives wooed doctors with food, gifts, and influence peddling, techniques which netted them both a huge portion of profits from opioid sales in Plaintiffs' geographic area, and nationwide. The sales forces of Abbott and Purdue worked in tandem, holding regular strategy sessions.

10. <u>Sun Pharmaceutical</u>

109. Defendant Sun Pharmaceuticals is a wholly owned subsidiary of Sun Pharmaceutical Industries Ltd. It manufactures, markets, and distributes drugs, including opioids, in the United States, including in Plaintiffs' geographic area.

11. Collegium

110. Defendant Collegium Pharmaceutical, Inc. ("Collegium") is a Virginia corporation with its principal place of business in Canton, Massachusetts.

111. Collegium manufactures, promotes, sells, and distributes opioids nationally and in Plaintiffs' geographic area, including the following opioids, as well as their generic versions:

Drug Name	Chemical Name	Form
Xtampza ER	Oxycodone	Tablet extended release

112. As of January 10, 2018, Collegium has signed a commercialization agreement with Depomed, Inc., which allows Collegium to market the opioid products Nucynta and Nucynta ER.

113. Collegium Vice President, Steven Passik, has proudly identified Dr. Portenoy as one of his mentors, stating that Dr. Portenoy, among others, "taught me everything I know about pain and encouraged and supported me long before I had any idea of what I was talking about."

114. In September 2016, the FDA's Office of Prescription Drug Promotion ("OPDP") sent advisory comments to Collegium regarding the company's presentations for Xtampza ER. In these advisory comments, OPDP recommended that Collegium revise its proposed presentations so that they did not misrepresent the approved indication or omit important context; misrepresent or omit important risk information; or omit other material information. In those comments, the OPDP also cautioned Collegium about failing to present risk information for Xtampza ER with a prominence and readability reasonably comparable to the presentation of benefits.

115. On February 9, 2018, the FDA sent a warning letter to Collegium regarding Collegium's exhibit booth advertisement of Xtampza ER at the American Society Health-System Pharmacists (ASHP) Summer Meetings 8c Exhibition, which was held on June 3-7, 2017. The warning letter referenced its September 2016 advisory comments to Colleguim and voiced "concern[ ] that Collegium is promoting Xtampza ER in a manner that fails to adequately present the very serious risks of the drug, despite this direction from OPDP." The warning letter stated that Collegium's exhibit booth "failed to adequately provide material information about the drug's limitations of use and the serious and life-threatening consequences that may result from the use of the drug, thereby creating a misleading impression about the drug's safety." The warning letter further stated that "the exhibit booth presentation included a principal display panel that prominently presented benefit claims about the abuse-deterrent properties of Xtampza ER, but failed to include any information with respect to the drug's limitations of use, which state that due to the risks of addiction, abuse, misuse, overdose and death, Xtampza ER should only be used in patients for whom alternative treatment options are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Nor did the principal display panel include any information with respect to the indication or serious and life-threatening risks... "

116. Collegium falsely stated in their presentation at the 2014 Jefferies Global Healthcare Conference that "prescription opioids remain the primary treatment for chronic pain[,]" although this was not (and is not) the case. Collegium repeated this false information in its March 2018 Form 10-K SEC filing.

117. On December 16, 2021, the Massachusetts Attorney General and Collegium entered into an assurance of discontinuance. "According to the AG's Office, Collegium sales representatives misled doctors about the potential risks of the drug by marketing it as a safe and

responsible alternative to other opioids, even though Xtampza has the same active ingredient (oxycodone) as other drugs like Oxycontin."[26]

12. Zydus

118. Defendant Zydus Pharmaceuticals (USA) Inc. is a company located in New Jersey.

119. At all relevant times, Zydus manufactured, marketed, and sold generic opioids throughout the United States and Plaintiffs' geographic area. Zydus manufactured, marketed, and sold opioids throughout Plaintiffs' geographic area, in violation of the duties owed to Plaintiffs in sufficient quantities to be a proximate cause of Plaintiffs' injuries.

120. As a generic manufacturer, Zydus failed to effectively and adequately communicate warnings in the labels of their products to prescribers and users. Zydus could have communicated the risks associated with the use of prescription opioid drugs through dear doctor or healthcare provider letters. However, Zydus had a financial incentive not to communicate these warning and risks and aggressively marketed its generic opioid products to drug distributors, prescription benefit managers, formularies, insurance companies, and other third parties to increase its own generic market share. Moreover, in the manufacture and sale of its opioid products, Zydus failed to report suspicious orders in violation of its duties under the Controlled Substances Act and local law and knowingly allowed widespread diversion to occur. See 21 C.F.R. § 1301.71(a).

13. Quest

121. Quest Pharmaceuticals, Inc. ("Quest") is a privately held company incorporated under the laws of Kentucky with its principal place of business in Kentucky.

122. Quest distributes prescription opioids to providers and retailers, including in Plaintiffs' geographic area.

[26] https://www.mass.gov/news/drug-company-ends-face-to-face-marketing-for-its-opioid-product-to-massachusetts-doctors-in-ag-settlement

123. At all times relevant to this Complaint, Quest distributed prescription opioids throughout the United States, including in and around Plaintiffs' geographic area.

14. KeySource

124. Defendant KeySource Medical, Inc. ("KeySource") is a corporation organized under the laws of Ohio with its principal place of business at 7820 Palace Drive Cincinnati, Ohio.

125. KeySource is a distributor of brand, generic, and specialty pharmaceuticals, including opioids, nationwide and in Florida.

126. At all times relevant to this Complaint, KeySource distributed prescription opioids in and around Plaintiffs' geographic area.

127. According to the Washington Post, "In May 2008, as the opioid epidemic was raging in America, a representative of the nation's largest manufacturer of opioid pain pills sent an email to a client at a wholesale drug distributor in Ohio. Victor Borelli, a national account manager for Mallinckrodt, told Steve Cochrane, the vice president of sales for KeySource Medical, to check his inventories and "[i]f you are low, order more. If you are okay, order a little more, Capesce?" Then Borelli joked, "destroy this email. . .Is that really possible? Oh Well. . ."[27]

128. Additionally, the Washington Post wrote, "DEA investigators also noticed that another wholesale drug company, KeySource Medical, operating out of Cincinnati, was pouring massive amounts of oxycodone into Florida. In 2010, it sent 41 million tablets of Mallinckrodt-made oxycodone to the state — nearly 2.5 pills for every man, woman and child. The DEA eventually revoked the registrations of Sunrise and KeySource, barring them from distributing controlled substances."[28]

[27] https://www.washingtonpost.com/investigations/internal-drug-company-emails-show-indifference-to-opioid-epidemic-ship-ship-ship/2019/07/19/003d58f6-a993-11e9-a3a6-ab670962db05_story.html.
[28] https://www.washingtonpost.com/investigations/interactive/2022/mallinckrodt-documents-doctors-sales/

129. On June 10, 2011, the DEA published a press release that provides, "Robert L. Corso, Special Agent in Charge of the Detroit Field Division, Drug Enforcement (DEA) announced today the immediate suspension of the federal controlled substance Registration of KeySource Medical, a wholesale supplier of pharmaceuticals. KeySource Medical, based in Cincinnati, Ohio, has been the subject of a DEA investigation that alleges the company was selling large quantities of controlled substances to pharmacies, primarily in Florida. The investigation has revealed that several of Keysource Medical's largest purchasers of oxycodone were engaged in schemes to dispense controlled substances based on prescriptions that were written for other than legitimate medical purposes. The investigation revealed that Keystone Medical distributed approximately 48 million dosage units of oxycodone products to customers in Florida over a two-year time between November of 2008 and November of 2010."[29]

15. Associated Pharmacies

130. Defendant Associated Pharmacies, Inc. ("Associated"), is an Alabama corporation with its principal place of business in Alabama. It distributed prescription opioids in the United States, including in Plaintiffs' geographic area.

131. At all times relevant to this Complaint, Associated distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in and around Plaintiffs' geographic area.

16. Albertsons

132. Defendant Albertsons Companies, Inc., is a Delaware corporation with its principal place of business in Boise, Idaho.

[29] https://www.dea.gov/press-releases/2011/06/10/cincinnati-pharmaceutical-suppliers-dea-license-suspended

133. Defendant Albertson's LLC is a Delaware limited liability company with its principal place of business in Boise, Idaho. Defendant Albertson's LLC is a wholly owned, direct subsidiary of Defendant Albertsons Companies, Inc.

134. Defendants Albertsons Companies, Inc. and Albertson's LLC are collectively referred to as "Albertsons."

135. Albertsons conducts business as a licensed pharmacy dispenser through its various DEA-registered subsidiaries and affiliated entities. At all times relevant to this Complaint, Albertsons operated licensed pharmacies in Plaintiffs' geographic area.

136. In addition, for a portion of the relevant time period, Albertsons operated as a distributor of controlled substances, distributing certain prescription opioids to its own pharmacies through Albertson's LLC Distribution Center #8720, located in Ponca City, Oklahoma.

137. Albertsons operates stores in 34 states and the District of Columbia under multiple store "banners," including Safeway, Savon, Vons, Jewel-Osco, Acme, Carrs, Randalls, Tom Thumb, and Market Street.

138. On information and belief, for some of the relevant time period, Albertsons operated an internal self-distribution network that supplied certain prescription opioids to pharmacies owned and operated by Albertsons. Albertsons distributed controlled substances through its distribution center in Ponca City, Oklahoma, registered as Albertson's LLC Distribution Center #8720.[30]

139. On information and belief, Albertsons lacked a suspicious order monitoring system for most of the time it operated its self-distribution network, relying on its employees' subjective evaluation of what constitutes a suspicious or unusual order.

[30] On information and belief, Albertsons' pharmacies also ordered controlled substances through McKesson, while Safeway pharmacies prior to 2015 ordered controlled substances primarily through Cardinal Health.

140. On information and belief, when Albertsons did implement an objective measure for detecting suspicious orders, it was based on a simple threshold that would be triggered by the size of the order only and not the frequency or pattern of the orders.

141. As described below, Albertsons' failure to establish effective controls against diversion with respect to its self-distribution of opioids was compounded by its failures to effectively monitor for dispensing red flags.

a. Albertsons Failed to Guard Against Diversion in Distributing and Dispensing in the Plaintiffs' Geographic Area.

142. The volume of opioids Albertsons brought into and dispensed in the County was so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

143. In addition, Albertsons also distributed and dispensed substantial quantities of prescription opioids and "cocktail" combinations in Plaintiffs' geographic area.

144. In Plaintiffs' geographic area, Albertsons violated the standard of care for a distributor and dispenser by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

145. As an operator of retail pharmacies, Albertsons had the ability to detect diversion in ways third-party wholesale distributors could not by examining the dispensing data from its own retail pharmacy locations.

146. Given the volume and pattern of opioids distributed in Plaintiffs' geographic area, Albertsons was, or should have been, aware that opioids were being oversupplied into the state and should have detected, reported, and rejected suspicious orders.

147. Albertsons was, or should have been, fully aware that the opioids and "cocktail" combinations being distributed and dispensed by it were likely to be diverted, yet it did not take meaningful action to ensure that it was complying with its duties and obligations with regard to controlled substances, including its responsibility to report suspicious orders and not to ship such orders unless and until due diligence allayed the suspicion.

148. Given Albertsons' retail pharmacy operations, in addition to its role as a wholesale distributor, Albertsons knew or reasonably should have known about the disproportionate flow of opioids into Plaintiffs' geographic area, and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, diversion.

b. Albertsons Failed to Effectively Identify and Investigate Dispensing Red Flags at Its Pharmacies.

149. Albertsons, throughout the relevant time period, owned and operated pharmacies throughout the United States, including pharmacies in the County. Through its wholly owned or controlled subsidiary companies, Albertsons operates over 1,700 retail pharmacies across the United States.

150. As described above, the volume of prescription opioids ordered and dispensed by Albertsons' pharmacies in and around Plaintiffs' geographic area is indicative of potential diversion and required appropriate due diligence.

151. As a dispenser of prescription opioids, Albertsons had visibility into dispensing-level data at all of its pharmacies, and Albertsons knew or should have known that it was dispensing an excessive volume of pills in Plaintiff's geographic area.

152. Upon information and belief, Albertsons, by virtue of the dispensing data available to it, had actual knowledge of indicia of diversion, such as (1) individuals traveling long distances

to fill prescriptions; (2) prescriptions for drug "cocktails" known for their abuse potential, such as oxycodone and Xanax; (3) individuals arriving together with identical or nearly identical prescriptions; (4) high percentage of cash purchases; and (5) doctors prescribing outside the scope of their usual practice or geographic area. However, Albertsons ignored these obvious red flags.

153. Upon information and belief, Albertsons failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

154. Discovery will reveal that Albertsons knew or should have known that its pharmacies in Plaintiffs' geographic area, as well as nearby states, were: (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, namely benzodiazepines or muscle relaxers; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non- controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. Albertsons had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

155. Albertsons had complete access to all prescription opioid distribution data related to its pharmacies in and around Plaintiffs' geographic area.

156. Albertsons had complete access to all prescription opioid dispensing data related to its pharmacies in and around Plaintiffs' geographic area.

157. Albertsons had complete access to information revealing the doctors who prescribed the opioids dispensed in its pharmacies in and around Plaintiffs' geographic area.

158. Albertsons had complete access to information revealing the customers who filled or sought to fill prescriptions for opioids in its pharmacies in and around Plaintiffs' geographic area.

159. Albertsons had complete access to information revealing the opioid prescriptions dispensed by its pharmacies in and around Plaintiffs' geographic area.

160. Albertsons had complete access to information revealing the geographic location of out-of-state doctors whose prescriptions for opioids were being filled by its pharmacies in and around Plaintiffs' geographic area.

161. Albertsons had complete access to information revealing the size and frequency of prescriptions written by specific doctors across its pharmacies in and around Plaintiffs' geographic area.

162. Upon information and belief, Albertsons failed to adequately use data available to it to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts or doses of opioids, or to adequately use data available to it to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

163. Upon information and belief, Albertsons also failed to adequately analyze and address its opioid sales to identify patterns regarding prescriptions that should not have been filled

and to create policies accordingly, or if it conducted such reviews, it failed to take any meaningful action as a result.

164. Albertsons is one of the largest food and drug retailers in the United States, with annual revenues of approximately $70 billion. As of February 2021, it operated 1,727 pharmacies across the United States.

165. In 2017, Albertsons agreed to pay $3 million to settle Department of Justice allegations that the company failed to timely report controlled substances that were missing from pharmacies. DOJ's investigation of Safeway (a wholly owned subsidiary of Albertsons) began when the DEA learned in 2014 that Safeway pharmacies in North Bend, Washington, and Wasilla, Alaska, did not notify the DEA of losses of tens of thousands of hydrocodone tablets until months after Safeway discovered the losses. DOJ then broadened its investigation to review practices at all Safeway pharmacies nationwide between 2009 and 2014 and found a widespread practice of Safeway pharmacies failing to timely report missing or stolen controlled substances.

166. In January 2020, Albertsons agreed to pay $1 million to resolve the DOJ's allegations that one of its pharmacies had committed numerous violations of the CSA. The DEA began investigating Albertsons' Osco Pharmacy #60 in Casper, Wyoming, during the course of investigating a Casper-based prescriber who prescribed over 2 million pills between 2011 and 2016 and was eventually sentenced to 25 years in prison for prescribing oxycodone without a legitimate medical purpose, including prescriptions that caused the death of an Arizona resident. While investigating this doctor's practices, the DEA began investigating the pharmacies filling his prescriptions and found numerous alleged violations by the Albertsons' Osco Pharmacy between October 2015 and February 2017. According to DOJ, "[i]nvestigators uncovered 128 instances of patients filling prescriptions for unusually large quantities and dosages of narcotics; patients

utilizing multiple pharmacies to fill prescriptions; or third parties filling prescriptions for out-of-state patients. Additional record keeping violations were also discovered."[31]

17. Winn-Dixie

167. Defendant Winn-Dixie Stores, Inc., ("Winn-Dixie") is a Florida Corporation with its principal place of business in Jacksonville, Florida. Winn-Dixie is registered as a licensed wholesale pharmaceutical distributor under the following named business entities: Winn-Dixie Logistics, Inc., Winn Dixie Logistics, LLC dba Winn-Dixie Pharmacy Warehouse #9002, and Winn Dixie Logistics. Winn Dixie distributed opioids, in violation of the duties owed to Plaintiffs in sufficient quantities to be a proximate cause of Plaintiff's injuries. Winn-Dixie is sued as both a Distributor Defendant and as Pharmacy Defendant.

168. At all times relevant to this Complaint, Winn-Dixie distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in and around Plaintiffs' geographic area.

18. Costco

169. Defendant Costco Wholesale Corporation ("Costco") is a Washington corporation with its principal place of business in Washington. At all times relevant to this Complaint, Costco dispensed prescription opioids and engaged in the retail sale of opioids throughout the United States, including in and near Plaintiffs' geographic area.

170. On January 19, 2017, the Department of Justice issue a press release titled, "Costco Wholesale to Pay $11.75 Million to Settle Allegations of Lax Pharmacy Controls - Costco Pharmacies Filled Prescriptions that Were Improper or Incomplete."[32] Additionally, it provides,

[31] U.S. Attorney's Office, District of Wyoming, *Casper Pharmacy Agrees to $1 Million Settlement of Allegations of Violations of the Controlled Substances Act* (Jan. 28, 2020), https://www.justice.gov/usao-wy/pr/casper-pharmacy-agrees-1-million-settlement-allegations- violations-controlled-substances.

[32] https://www.justice.gov/opa/pr/costco-wholesale-pay-1175-million-settle-allegations-lax-pharmacy-controls

"Costco Wholesale will pay $11.75 million to settle allegations that its pharmacies violated the Controlled Substances Act when they improperly filled prescriptions for controlled substances. The settlement resolves allegations that Costco pharmacies filled prescriptions that were incomplete, lacked valid Drug Enforcement Administration (DEA) numbers or were for substances beyond various doctors' scope of practice. Additionally, the settlement resolves allegations that Costco failed to keep and maintain accurate records for controlled substances at its pharmacies and centralized fill locations."[33] Further, it provides, "Under the settlement reached Jan. 18, 2017, Costco acknowledges that between Jan. 1, 2012 and Dec. 31, 2015, certain Costco Pharmacies dispensed controlled substances inconsistent with their compliance obligations under the Controlled Substances Act (CSA) and its implementing regulations. The violations include filling prescriptions from practitioners who did not have a valid DEA number; incorrectly recording the practitioner's DEA number; filling prescriptions outside the scope of a practitioner's DEA registration; filling prescriptions that did not contain all the required information; failing to maintain accurate dispensing records; and failing to maintain records for their central fill locations in Sacramento, California, and Everett, Washington."[34]

19. Target

171. Defendant Target Corporation ("Target") is a Minnesota corporation with its principal place of business in Minneapolis, Minnesota.

172. At all times relevant to this Complaint, Target dispensed prescription opioids and engaged in the retail sale of opioids throughout the United States, including in and near Plaintiffs' geographic area.

20. Publix

[33] *Id.*
[34] *Id.*

173. Defendant Publix Super Markets, Inc. ("Publix") is a Florida corporation with its principal place of business in Lakeland, Florida. Publix, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. Publix also operates retail stores, including in and around Plaintiffs' geographic area, that sell prescription medicines, including opioids.

174. At all times relevant to this Complaint, Publix distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in and around Plaintiffs' geographic area.

175. Publix operates approximately 1,264 supermarkets across Florida, Georgia, Alabama, North and South Carolina, Tennessee, and Virginia. Most, if not all of Publix supermarkets include a pharmacy.

176. As of 2014, Publix operated 929 pharmacies in the southeastern United States, with sales exceeding $2.2 billion annually.

177. In both its capacity as a distributor and as a dispenser of controlled substances, Publix failed to implement effective policies and practices to prevent diversion of opioids in and around Plaintiffs' community.

178. During the time period relevant to Plaintiff's claims, Publix acted as both a distributor of controlled substances to its own pharmacies and a retailer dispensing controlled substances. Publix warehoused and self-distributed controlled substances to its stores, including opioids, from a warehouse devoted to pharmacy products in Orlando, Florida ("Orlando Warehouse").

a. Publix Failed to Maintain Effective Controls Against Diversion at the Wholesale Level.

179. Publix failed to implement an effective suspicious order monitoring program.

180. Publix distributed and continues to distribute controlled substances to its own Publix stores. Publix distributed to the County through its Orlando Warehouse, a DEA registrant. As of 2012, the Orlando Warehouse shipped to all Publix pharmacies two to three times per week.

181. Publix supplemented its own self-distribution of opioids with distribution by industry players, including McKesson and AmerisourceBergen. Even if Publix's distribution center reduced an order to a smaller number of bottles, nothing prevented a Publix pharmacy from making up the difference by ordering opioids from third party distributors, such as McKesson and AmerisourceBergen. Not only could Publix pharmacies place another order with these outside vendors to make up the difference, but they could have orders fulfilled by both Publix and a third-party distributor at the same time.

182. Ultimately, Publix's distribution system made it nearly impossible for any order to be identified, much less reported, as suspicious. Publix placed orders of controlled substances from manufacturers and distributors who prioritized sales goals over suspicious order monitoring duties. Publix also gave significant latitude to its employees to manipulate order size and thresholds. As a result of the company's policies and procedures, Publix did not—and indeed, could not—identify what was unusual.

183. In 2015, a Teva employee, Joe Tomkiewicz, identified a potentially suspicious order by Publix through Anda, Inc., which was then one of Teva's wholesaler customers. Tomkiewicz identified "serious red flags" with regard to the Publix order, including:

> 1. This is high-strength oxycodone ultimately going to Florida, a well-established hot spot for oxycodone abuse in the U.S.
> 2. The total quantities in the Publix forecast put them significantly above their peers as far as size and class of trade are concerned.
> 3. The breakdown by strength, with an emphasis on 40mg does not appear to be normal for a retail pharmacy. I would expect the breakdown to be closer to that of Thrifty White, where the emphasis is on lower strengths.

184. Tomkiewicz was ultimately pressured by Teva's Director of National Accounts, Jocelyn Baker, to overlook the "serious red flags" in Publix's order and permit the order to process.

Ms. Baker highlighted Publix's importance as customer as the reason, "Publix is an established customer who sells some of our other control[led substances]," and "[t]his was not presented to them in advance and may put this award at risk."

185. Distributor McKesson provided Publix with notification of stores hitting McKesson's thresholds and regularly granted threshold increases without conducting any due diligence.

186. For example, in 2009, McKesson alerted Publix employees Chris Hewell, Paul Hines, and Ivonne Leon, that several of its accounts were over 80% of their authorized threshold, with "[s]everal stores already at 100%." Publix employee Chris Hewell, Manager of Procurement, responded, requesting "amnesty" from the ordering threshold program, thus permitting Publix to exceed the standard 80% threshold for ordering Oxycodone. While Ms. Martindale's initial internal response was, "I'm pretty sure this isn't something we can do," McKesson ultimately granted Publix a temporary 2000 dosage unit increase "across the board."

187. Publix allowed its individual stores to order from third party distributors without any restrictions or limited restrictions, and upon information and belief, did not sufficiently take those orders into account in Publix's self-distribution SOM system, negating any constraints from Publix's internal controls.

188. For example, in 2013, Lucy Bard, National Account Manager at Purdue, reported to her superiors at Purdue that after calling on several Publix pharmacies in St. Petersburg, Florida, "[n]ot one pharmacist has experience a push back with ordering OxyContin or maximizing their quantities per McKesson/DEA regulations."

b. Publix Failed to Maintain Effective Controls Against Diversion in Plaintiffs' Geographic Area.

189. Publix violated the standard of care for a distributor by failing to: (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities it knew or should have known could not be justified and signaled potential diversion.

190. As a vertically integrated distributor and dispenser of prescription opioids, Publix knew or should have known that an excessive volume of pills was being sold into Plaintiffs' geographic area and ultimately, onto its streets. Publix's activities as a distributor and a seller or dispenser of opioids are inextricably linked.

191. Publix funneled far more opioids into Plaintiffs' geographic area, and out of its pharmacy doors, than could have been expected to serve legitimate medical use, and ignored other indicia of diversion, including but not limited to suspicious orders.

192. It cannot be disputed that Publix was aware of the suspicious orders that flowed from its distribution facilities into its own stores. Publix simply refused to identify, investigate, and report suspicious orders even though Publix knew, or should have been fully aware, that opioids it distributed and sold were likely to be diverted. Conversely, Publix failed to report suspicious orders, failed to meaningfully investigate, or reject suspicious orders, and failed to prevent diversion, or otherwise control the supply of opioids flowing into Plaintiffs' geographic area.

193. Upon information and belief, Publix failed to analyze: (a) the number of opioid prescriptions filled by its pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; and (c) the number of opioid prescriptions filled relative to other drugs.

194. Publix was, or should have been, fully aware that the opioids being distributed and dispensed by it were likely to be diverted. Yet it did not take meaningful action to investigate or to ensure that it was complying with its duties and obligations with regard to controlled substances,

including its responsibility to report suspicious orders and not to ship such orders unless and until due diligence allayed the suspicion.

195. Given Publix's retail pharmacy operations, in addition to its role as a wholesale distributor, Publix knew, or reasonably should have known, about the disproportionate flow of opioids into Plaintiffs' geographic area and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for, if not direct evidence of, illicit supply and diversion.

196. In addition, and upon information and belief, Publix knew, or deliberately turned a blind eye to, its pharmacies' role in diversion of dangerous drugs. At the pharmacy level, discovery will reveal that Publix knew, or should have known, that its pharmacies in Plaintiffs' geographic area and surrounding areas, were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Publix had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

197. Failures regarding dispensing in Publix's Florida stores also allowed diverted opioids to be funneled into surrounding states and demonstrated the failures of Publix systems.

198. Because of its vertically integrated structure, Publix has access to complete information regarding red flags of diversion across its pharmacies in and around Plaintiffs' geographic area, but Publix chose not to utilize this information and failed to effectively prevent diversion.

c. Publix Failed to Implement Effective Policies and Procedures to Guard Against Diversion from its Retail Stores.

199. At all times relevant herein, Publix pharmacies sold controlled substances, including FDA Schedule II and FDA Schedule III controlled substances otherwise known as opiate narcotics or opioids.

200. "Publix Supermarkets, Inc.," not any individual Publix store, is the DEA registrant for each of Publix's pharmacies across the country.

201. As described above, Publix pharmacies ordered and were supplied opioids from a combination of outside vendors and Publix's own Orlando Warehouse.

202. Upon information and belief, Publix lacked meaningful policies and procedures to guide its pharmacy staff in maintaining effective controls against diversion.

203. Publix's conduct and the volume it dispensed in Plaintiffs' geographic area thereafter indicates that, to the extent any policies existed, those policies were not consistently and reliably applied. In addition, as discussed further below, Publix pressured pharmacists to put profits ahead of safety.

204. Upon information and belief, Publix failed to use data held at the corporate level to assist pharmacists in evaluating red flags of diversion.

d. Publix Failed to Guard Against Diversion in Dispensing to Plaintiffs' Geographic Area.

205. Upon information and belief, Publix pharmacies routinely have dispensed opioids in violation of the Controlled Substances Act and accompanying regulations. Such conduct was a

result of Publix's lack of robust policies and procedures regarding dispensing controlled substances as well as Publix's focus on profitability over its legal obligations and public safety.

206. As a sophisticated chain pharmacy, Publix had the ability to analyze data relating to drug utilization and prescribing patterns across multiple retail stores in diverse geographic locations. Its own data would have allowed Publix to observe patterns or instances of dispensing that are potentially suspicious of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper or illegitimate prescribing.[35]

207. Publix did not use data available to it to effectively comply with its legal obligations to prevent diversion and ensure only legal prescriptions were being filled at its pharmacies.

208. Upon information and belief, Publix provided its pharmacists no or limited visibility into the data it collected, thereby depriving them of an invaluable resource when evaluating prescriptions.

209. Publix did not make it possible, much less easy, for pharmacists to share information about red flags, suspicious prescribers, and suspicious patients.

210. To the extent Publix did provide its pharmacists with any visibility into the data it collected, Publix deprived its pharmacists of the ability to meaningfully review and apply this data by making such significant demands on its pharmacists that it effectively prevented them from properly evaluating potential red flags, suspicious prescribers, and suspicious patients.

211. For example, a current job posting for a "Pharmacist – 30-hour Floater" in a Marietta, Georgia Publix store lists an overwhelming list of skills needed for an applicant:

[35] *See, e.g.*, Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195, 77 Fed. Reg. 62,315 (Dep't of Justice Oct. 12, 2012) (decision and order) (DEA expert witness examined dispensing records alone to identify inappropriately dispensed medications).

- provide dedication to each pharmacies success, by executing strategy, motivating and inspiring staff as the pharmacist-on-duty
- set priorities to maximize contribution, executing daily tasks, supporting the team and building rapport with both customers and associates
- provide best-in-class pharmacy service to patients, empower your staff in providing value and service through counseling, building personalized relationships, promoting customer loyalty, offering pharmacist led clinical services to improve health and wellness and preventative care through services available at Publix
- inspire each team you work with to do the right thing, gaining buy in, and empowering the team to be accountable
- provide enthusiasm for all new pharmacy initiatives at your assigned location
- manage team performance, such as prescription promised time, by assigning tasks to ensure complex operational activities are met in a timely and efficient manner in the absence of the pharmacist-in-charge
- use best practices to make sound business decisions while covering as the pharmacist-on-duty
- be regarded as an expert on the pharmacy technology system and how it is used for both routine and complex prescription processing
- mentor others on Publix pharmacy best practices to maximize sales, minimize shrink while meeting customers' needs, using programs such as auto refill and Sync Your Refills
- proactively advance pharmacy clinical initiatives including Medication Therapy Management (MTM), pharmacist point-of-care testing, immunizations, and diabetes management

212. The laundry list of responsibilities included in the "Pharmacist – 30-hour Floater" posting repeatedly highlights a pharmacist's role in pharmacy success, maximizing sales, meeting customers' needs, and gaining customer loyalty, still, the responsibilities list makes no mention of a pharmacist's role in identifying and evaluating potential red flags, suspicious prescribers, and suspicious patients.

213. In addition, Publix placed strict emphasis on its pharmacists filling prescriptions as quickly as possible while Publix simultaneously limited resources available to assist pharmacists.

214. While the above job description details that the pharmacist must inspire staff and teamwork, in reality, many Publix pharmacists lament publicly that Publix pharmacists often work without the aid of a pharmacy technician or other staff. When pharmacy technicians are unavailable or pulled away to other areas in the supermarket, Publix pharmacists are forced to work alone, and

to act as both pharmacist and technician. This lack of resources or aid impairs a pharmacist's ability to address patient safety and patient care, including his or her ability evaluate potential red flags, suspicious prescribers, and suspicious patients.

215. The problem of illegal dispensing caused by Publix's focus on quickly filling prescriptions and increasing the number of prescriptions dispensed was exacerbated by Publix's inadequate pharmacy staffing. This greatly cut into the ability of the pharmacist to evaluate each prescription carefully and in accordance with the law.[36]

216. In addition, the job posting for "Pharmacist – 30-hour Floater" position states the position is eligible for a "Retail bonus" benefit which is paid quarterly and is "based on sales and profits that are calculated at the end of each inventory period."

217. Publix's compensation structure presents a conflict of interest for pharmacists on at least one front as it incentivizes pharmacists to fill as many prescriptions as possible to increase the store profit metric. In this structure, a pharmacist would necessarily receive a higher bonus for filling illegitimate prescriptions (by increasing store profits). On the other hand, rejecting illegitimate prescriptions would decrease overall sales and profits, and decrease the final bonus amount a pharmacist could receive.

21. <u>Smith Drug</u>

218. Defendant Smith Drug Company is a South Carolina corporation with its principal place of business in South Carolina. Smith Drug, and through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor.

[36] Some states have tried to outlaw pharmacists from working alone. California, for example, passed a law saying no pharmacist could be required to work alone. Regrettably, however, it has been largely ignored since taking effect in 2019, according to leaders of a pharmacists' union. See Gabler, Ellen, How Chaos at Chain Pharmacies is Putting Patients at Risk, THE NEW YORK TIMES (Jan. 31, 2020), https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html.

219. Smith Drug Company is a division of J M Smith Corporation responsible for operating JM Smith Corporation's pharmaceutical distribution business. J M Smith Corporation and Smith Drug Company are referred to as "Smith Drug" throughout this Complaint.

220. Smith Drug is a wholesale pharmaceutical distributor primarily serving the eastern United States. At all relevant times, Smith Drug operated as a licensed pharmacy wholesaler in Florida and delivered substantial amounts of opioid drugs to buyers in this State. Smith Drug operates a distribution center in Valdosta, Georgia.

221. At all times relevant to this Complaint, Smith Drug distributed prescription opioids throughout the United States, including in and around Plaintiffs' geographic area.

22. Henry Schein

222. Henry Schein, Inc. describes its business as providing a comprehensive product and services offerings to integrated health systems, designed specifically for and focused exclusively on, the non-acute care space. Henry Schein, Inc. is incorporated in Delaware, with its principal place of business located in Melville, New York, and registered to do business in Florida and may be served through its registered agent: Corporation Service Company, 1201 Hays Street, Tallahassee, Florida 32301-2525.

223. At all times relevant to this Complaint, henry Schein distributed prescription opioids throughout the United States, including in and around Plaintiffs' geographic area.

224. Henry Schein, Inc. distributes, among other things, branded and generic pharmaceuticals to customers that include dental practitioners, dental laboratories, animal health practices and clinics, and office-based medical practitioners, ambulatory surgery centers, and other institutions.

225. Henry Schein Medical Systems, Inc. ("Henry Schein Medical") is a subsidiary of Henry Schein, Inc., that provides practice management, electronic medical records, and document management for medical groups.

226. Henry Schein Medical Systems Inc. has been registered to do business with the State of Ohio since at least 1987. In November of 2014, Henry Schein Medical and Cardinal Health entered into a strategic partnership, which consolidated Cardinal Health's physician office sales organization into Henry Schein Medical. Henry Schein took responsibility for serving physician offices, and through its "symbiotic" arrangement with Cardinal Health, gained access to over 25,000 physical offices as customer locations.[37] As a result of this agreement, Henry Schein Medical added more than $300 million in annual sales.

227. Henry Schein, Inc. and Henry Schein Medical Systems Inc. are referred to as "Henry Schein." At all relevant times, Henry Schein was in the business of distributing, and redistributing, pharmaceutical products to consumers within Plaintiffs' geographic area.

228. In 2015, Henry Schein reported that its sales reached a record $10.4 billion and that it had grown at a compound annual rate of approximately 16 percent since becoming a public company in 1995. Overall, it is the world's largest provider of health care products and services to office-based dental, animal health, and medical practitioners.

229. The Pharmacy Benefit Manager Defendants ("PBM Defendants") are defined below. At all relevant times the PBM Defendants acted as the gatekeepers of prescription drugs including opioids. Pharmacy benefit managers ("PBMs") negotiate with drug manufacturers to offer preferred drug formulary placement for the manufacturers' drugs. PBMs establish reimbursement rates for the drugs dispensed. PBMs earn revenue from at least the following

[37] Raymond Davis, Henry Schein and Cardinal, The J. of Healthcare Contracting, Feb. 12, 2018, http://www.jhconline.com/henry-schein-and-cardinal.html.

sources: fees from health plans and insurers, rebates, and other incentives such as volume target bonuses negotiated with drug manufacturers, and fees from maintaining pharmacy networks.[38]

23. Express Scripts

230. Defendant, Express Scripts Holding Company ("ESHC"), is a Delaware corporation with its principal place of business in St. Louis, Missouri. ESHC is registered to do business in Florida through its subsidiary Express Scripts Inc., Express Scripts Administrators, LLC, Express Scripts Pharmacy, Inc., Express Scripts Sales Operations, Inc., Express Scripts Services Company and Express Scripts Utilization Management Co.

231. Defendant, Express Scripts, Inc. ("ESI"), is incorporated in the State of Delaware with its principal place of business located in St. Louis, Missouri, is a pharmacy benefit management company, and is a wholly owned subsidiary of ESHC. ESI is registered to do business in Florida and may be served through its registered agent: C T Corporation System, 1200 South Pine Island Road, Plantation, Florida, 33324.

232. In 2012, ESI acquired its rival, Medco Health Solutions Inc., in a $29.1 billion deal. As a result of the merger, ESHC was formed and became the largest PBM in the nation, filling a combined 1.4 billion prescriptions for employers and insurers.[39]

233. According to the Pharmacy Benefit Management Institute, in 2015, Express Scripts was the top ranking PBM nationwide with twenty-six percent (26%) of the industry market share.[40]

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[38] Health Policy Brief, On behalf of payers, pharmacy benefit managers negotiate rebates from drug makers in exchange for preferred formulary placement, HEALTH AFFAIRS, Sep. 14, 2017, https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/

[39] Peter Frost, Express Scripts closes $29.1-billion purchase of Medco, LOS ANGELES TIMES (Apr. 3, 2012), http://articles.latimes.com/2012/apr/03/business/la-fi-medco-20120403

[40] PBM Market Share, by Total Prescription Claims, 2015, PHARMACY BENEFIT MANAGEMENT INSTITUTE, INDUSTRY RESEARCH, https://www.pbmi.com/PBMI/Research/Industry_Research/PBMI/Research/PBMI___Industry _Research .aspx?hkey=22023612-80c4-4ada-a17e-85e7dfcbc1f8

234. Express Scripts derives substantial revenue managing pharmacy benefits in Plaintiffs' geographic area through the services it provides and the formulary it maintains in its relationships with health plans.

24. United Health

235. Defendant, UnitedHealth Group Incorporated ("UnitedHealth"), is a Delaware corporation with its principal place of business located in Minnetonka, Minnesota and is a diversified managed health care company with two business platforms. UnitedHealth serves approximately 115 million individuals throughout the United States, including Plaintiffs' geographic area. For 2016, UnitedHealth reported an operating income of $12.9 billion.

236. UnitedHealth derives substantial revenue managing pharmacy benefits in Plaintiffs' geographic area through the services it provides and the formulary it maintains in its relationships with health plans.

25. Medco

237. Express Scripts, Inc. acquired Defendant Medco Health Solutions Inc. in 2012 in a $29.1 billion deal. As a result of the merger, Defendant Express Scripts Holding Company ("ESHC") was formed and became the largest PBM in the nation, filling a combined 1.4 billion prescriptions for employers and insurers. Defendant Express Scripts Holding Company is a Delaware corporation with its principal place of business in St. Louis Missouri. Medco Health Solutions, Inc. can be served at c/o The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801.

238. Defendant Merck-Medco was established in mid-2002 by Merck & Co as its pharmacy benefits management subsidiary, as a separate, publicly traded company.

239. According to its SEC filing, in August 2003, Merck & Co. approved a spin-off, called Medco Health Solutions, Inc., a "wholly owned subsidiary of Merck that provides pharmacy benefit management services to approximately 62 million members.'

240. Upon information and belief, Merck-Medco is the corporate predecessor of Medco Health Solutions Inc., collectively referred to herein as "Medco".

241. Medco derives substantial revenue managing pharmacy benefits in Plaintiffs' geographic area through the services it provides and the formulary it maintains in its relationships with health plans.

26. Optum

242. Defendant, Optum, Inc., is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. Optum, Inc. is a health services company managing the subsidiaries that administer UnitedHealth's pharmacy benefits, including OptumRX, Inc. On information and belief, Optum, Inc. is a subsidiary of UnitedHealth.

243. Defendant, OptumRx, Inc., is a Delaware corporation with its principal place of business located in Irvine, California. OptumRx operates as a subsidiary of OptumRx Holdings, LLC, which in turn operates as a subsidiary of Optum, Inc. OptumRx operates as the PBM for UnitedHealth, collectively referred to herein as "Optum".

244. OptumRx, Inc. is registered to do business in Florida and may be served through its registered agent CT Corporation System, C T Corporation System, 1200 S. Pine Island Road, Plantation, Florida, 33324.

245. At all times relevant hereto, OptumRx derives substantial revenue providing pharmacy benefits in Plaintiffs' geographic area through several different means.

246. According to the Pharmacy Benefit Management Institute, OptumRx (UnitedHealth) was the third highest ranking PBM in 2015 with twenty-two (22%) of the industry market share.[41]

247. In one case, OptumRx, which is owned by UnitedHealth, suggested that a member taking Butrans consider switching to a "lower cost alternative," such as OxyContin or extended-release morphine, according to a letter provided by the member. Mr. Wiggin, the UnitedHealthcare spokesman, said the company's rules and preferred drug list "are designed to ensure members have access to drugs they need for acute situations, such as post-surgical care or serious injury, or ongoing cancer treatment and end of life care, as well as for long-term use after alternatives are tried."[42]

248. "UnitedHealthcare places morphine on its lowest-cost drug coverage tier with no prior permission required, while in many cases excluding Butrans. And it places Lyrica, a nonopioid, brand-name drug that treats nerve pain, on its most expensive tier, requiring patients to try other drugs first."[43]

27. <u>Navitus</u>

249. Defendant, Navitus Holdings, LLC, is a limited liability company organized under the laws of Wisconsin with its principal place of business located in Madison Wisconsin. Navitus Holdings, LLC may be served through its registered agent: CT Corporation System, 301 South Bedford Street, Suite 1, Madison, Wisconsin 53703.

250. Defendant, Navitus Health Solutions, LLC, a pharmacy benefit manager, is a limited liability company organized under the law of Wisconsin with its principal place of business

[41] Pharmacy Benefit Management Institute, Industry Research, supra note 35.
[42] Katie Thomas and Charles Ornstein, Amid Opioid Crisis, Insurers Restrict Pricey, Less Addictive Painkillers, THE NEW YORK TIMES, Sep. 17, 2017, https://www.nytimes.com/2017/09/17/health/opioid-painkillers-insurancecompanies.html?mwrsm=Email
[43] *Id.*

located in Madison, Wisconsin and is a wholly owned subsidiary of Navitus Holdings, LLC. Navitus Health Solutions, LLC is registered to do business in Florida and may be served through its registered agent: C T Corporation System, 1200 South Pine Island Road, Plantation, Florida 33324.

251. Navitus Holdings, LLC and Navitus Health Solutions, LLC are collectively referred to as "Navitus."

252. Navitus derives substantial revenue managing pharmacy benefits in Plaintiffs' geographic area through the services it provides and the formulary it maintains in its relationships with health plans.

253. The opioids at issue in this case were reimbursed by the PBM Defendants. Without the PBM Defendant reimbursement for the opioids at issue herein, the opioids would not have entered the marketplace and the entire scheme would have failed.

FACTS RELEVANT TO ALL CAUSES OF ACTION

A. Background on Pain Medicine.

1. Safe and Effective Treatment of Chronic Pain Centers on Informed Risk Management.

254. The practice of medicine centers on informed risk management. Prescribers must weigh the potential risks and benefits of each treatment option, as well as the risk of non-treatment.

255. Accordingly, the safe and effective treatment of chronic pain requires that a physician be able to weigh the relative risks of prescribing opioids against both (a) the relative benefits that may be expected during the course of opioid treatment and (b) the risks and benefits of alternatives.

256. This bedrock principle of full disclosure is particularly important in the context of chronic opioid therapy because of the risk that patients will become physically and psychologically dependent on the drugs, finding it difficult to manage or terminate their use.

257. The FDA-approved drug labels on each of Defendants' opioids do not attempt to advise physicians how to maximize the benefits and minimize the risks for patients on long-term chronic opioid therapy. The labels contain no dosing cap above which it would be unsafe for any doctor to prescribe to any patient. Nor do any of the labels provide a duration limit, after which the risks to a patient might increase. Thus, doctors and patients rely more heavily on educational materials such as treatment guidelines, CMEs, and scientific and patient education articles and websites to inform their treatment decisions.

2. Opioid Use Is Associated with Known and Substantial Risks.

258. Opium has been recognized as a tool to relieve pain for millennia; so has the magnitude of its potential for abuse, addiction and its dangers. Opioids are related to illegal drugs like opium and heroin. In fact, types of fentanyl, a widely-distributed opioid in the United States, have now been made illegal in China.

259. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain – particularly on the battlefield – and they were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants and beverages. By 1900, an estimated 300,000 people were addicted to opioids in the United States.[44] Many doctors prescribed opioids solely to avoid patients' withdrawal. Both the numbers of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.

[44] Substance Abuse and Mental Health Services Administration, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (TIP Services), No. 43 (2005).

260. Beginning in the late 20th century and continuing through today, the pharmaceutical industry acted to dramatically expand the marketplace for opioids. As set forth below, pharmaceutical actors facilitated this expansion in three ways. First, pharmaceutical manufacturers engaged in a misinformation campaign which altered public perception of opioids, and deceived doctors, federal regulators, and the general public about their addictive qualities. Second, PBMs ensured that opioids were widely available, regularly prescribed and reimbursed. Third, opioid manufacturers and wholesalers/distributors flouted their federally imposed requirements to report suspicious opioid orders to the DEA and state agencies. These facilitated an explosion in the illegitimate marketplace for prescription opioids.

261. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression," as the result of an excessive dose.

262. Studies and articles from the 1970s and 1980s also made the reasons to avoid opioids clear. Scientists observed negative outcomes from long-term opioid therapy in pain management programs; opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, and even prohibited, the use of opioid therapy for chronic pain.

263. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain,

and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the patient had been using opioids.

264. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses to obtain the same levels of pain reduction to which he or she has become accustomed – up to and including doses that are "frighteningly high."[45] At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take the opioids at continuously escalating dosages to match pain tolerance and still overdose at recommended levels.

265. Dr. Andrew Kolodny, Chief Medical Officer for Phoenix House, a national addiction treatment program, has explained the effect of opioids as akin to "hijack[ing] the brain's reward system," which in turn convinces a user that "the drug is needed to stay alive."[46] A patient's fear of the unpleasant effects of discontinuing opioids combined with the negative reinforcement during a period of actual withdrawal can drive a patient to seek further opioid treatment—even where ineffective or detrimental to quality of life—simply to avoid the deeply unpleasant effects of withdrawal.

266. Patients that receive high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer an overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to an overdose even when opioids are taken as recommended.

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[45] M. Katz, Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith, 170(16) Archives of Internal Med. 1422 (2010).

[46] David Montero, *Actor's Death Sows Doubt Among O.C.'s Recovering Opioid Addicts*, The Orange Cnty. Reg. (Feb. 3, 2014), http://www.ocregister.com/articles/heroin-600148-shaffer-hoffman.html (accessed May 30, 2017).

267. Further, "a potential side effect from chronic use [of opioids] can be abuse and addiction . . . [i]n fact, correct use and abuse of these agents are not polar opposites—they are complex, inter-related phenomena."[47] It is very difficult to tell whether a patient is physically dependent, psychologically dependent, or addicted. Drug-seeking behaviors, which are signs of addiction, will exist and emerge when opioids are suddenly not available, the dose is no longer effective, or tapering of a dose is undertaken too quickly.

268. Studies have shown that between 30% and 40% of long-term users of opioids experience problems with opioid use disorders.[48]

269. Each of these risks and adverse effects—dependence, tolerance, and addiction—is fully disclosed in the labels for each of Defendants' opioids (though, as described below, not in Defendants' marketing).[49] Prior to Defendants' deceptive marketing scheme, each of these risks was well-recognized by doctors and seen as a reason to use opioids to treat chronic pain sparingly and only after other treatments had failed.

270. Opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours.

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[47] Wilson M. Compton & Nora D. Volkow, *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies*, 81(2) Drug & Alcohol Dependence 103, 106 (2006).

[48] Joseph A. Boscarino et al., *Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system*, 105(10) Addiction 1776 (2010); Joseph A. Boscarino et al., *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria*, 30(3) Journal of Addictive Diseases 185 (2011).

[49] For example, Purdue's OxyContin label (October 5, 2011) states: "Physical dependence and tolerance are not unusual during chronic opioid therapy."

271. Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them with short-acting, rapid- onset opioids for episodic pain.

272. While it was once thought that long-acting opioids would not be as susceptible to abuse and addiction as short-acting ones, this view has been discredited. OxyContin's label now states, as do all labels of Schedule II long-acting opioids, that the drug "exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death." The FDA has required extended release and long-acting opioids to adopt "Risk Evaluation Mitigation Strateg[ies]" on the basis that they present "a serious public health crisis of addiction, overdose, and death."[50]

In 2013, in response to a petition to restrict the labels of long-acting opioid products, the FDA noted the "grave risks" of opioids, "the most well-known of which include addiction, overdose, and even death."[51] The FDA further warned that "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death."[52] The FDA required that—going forward—opioid makers of long-acting formulations clearly communicate these risks in their labels. Thus, the FDA confirmed what had previously been accepted practice in the treatment of pain— that the adverse outcomes from opioid use include "addiction, unintentional overdose, and death" and that long-acting or extended-release opioids "should be used ***only when alternative treatments are inadequate***."[53]

273. Notably, in reaching its conclusion, the FDA did not rely on new or otherwise previously unavailable scientific studies regarding the properties or effects of opioids.

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[50] FDA, *Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting Opioids* (last updated Oct. 9, 2014), http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm (accessed May 30, 2017).

[51] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[52] *Id.*

[53] *Id.* at 7 (emphasis in original).

274. The FDA-approved labels on each of Defendant's opioids do not attempt to advise physicians on how to maximize the benefits and minimize the risks for patients on long term opioid therapy. The labels contain no dosage cap above which it would be unsafe to prescribe to any patient. Nor do they provide a duration limit. Doctors and patients rely heavily on education materials, such as treatment guidelines, CMEs, and scientific and patient education articles and websites, to inform their treatment decisions.

275. On July 25, 2012, the Physician For Responsible Opioid Prescribing ("PROP"), a non-profit organization made up of doctors and other health care professionals, petitioned the FDA to change the labeling of opioid medications. The petition was signed by thirty-seven physicians located nationwide. In its letter to the FDA, the group stated that "an increasing body of medical literature suggests that long term-use of opioids may be neither safe nor effective for many patients, especially when prescribed in high doses."[54]

276. In its petition, PROP also stated that "many clinicians are under the false impression that chronic opioid therapy (COT) is an evidence-based treatment for chronic non-cancer pain" and that "these misconceptions lead to overprescribing and high dose prescribing." It was also their opinion that "the current label on opioid analgesics does not comply with [FDA law]".

277. As the basis for its petition, PROP provided "Statements of Scientific Basis for Petition" which provided a list of detailed reports and studies proving the risks of opioid medications, the high risk of addiction, the exaggerated and false benefits, and further medically backed reasons to change the labelling of opioid medications to reduce prescribing.

278. In 2013, in response to a petition to require manufacturers to strengthen warnings on the labels of long-acting opioid products, the FDA warned of the "grave risks" of opioids, including "addiction, overdose, and even death." The FDA further warned, "[e]ven proper use

[54] July 25, 2012, letter from PROP to FDA, accessed at http://www.citizen.org/documents/2048.pdf on May 30, 2017.

of opioids under medical supervision can result in life- threatening respiratory depression, coma, and death." Because of those grave risks, the FDA said that long-acting or extended- r e l e a s e opioids "should be used only when alternative treatments are inadequate."[55] The FDA required that – going forward – opioid makers of long-acting formulations clearly communicate these risks on their labels.

279. In 2016, the FDA expanded its warnings for immediate-release opioid pain medications, requiring similar changes to the labeling of immediate-release for opioid pain medications as it had for extended-release opioids in 2013. The FDA also required several additional safety-labeling changes across all prescription opioid products to include additional information on the risk of these medications.[56]

280. The facts on which the FDA relied in 2013 and 2016 were well known to Defendants for many years since they began marketing these drugs.

3. Long-Term Opioid Use Benefits Are Unproven and Contradicted.

281. Despite the fact that opioids are now routinely prescribed, there has never been evidence of their safety and efficacy for long-term use.

282. Defendants have always been aware of these gaps in knowledge. While promoting opioids to treat chronic pain, Defendants have failed to disclose the lack of evidence to support their long-term use and have failed to disclose the contradictory evidence that chronic opioid therapy actually makes patients sicker.

283. There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function long-term. The first random, placebo-

[55] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing*, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013) (emphasis in original).

[56] FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm (accessed May 30, 2017).

controlled studies appeared in the 1990s, and revealed evidence only for short-term efficacy and only in a minority of patients.[57]

284. A 2004 report reviewed 213 randomized, controlled trials of treatments for cancer pain and showed that, while opioids had short-term efficacy, the data was insufficient to establish long-term effectiveness. Subsequent reviews of the use of opioids for cancer and non-cancer pain consistently note the lack of data to assess long-term outcomes. For example, a 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and that evidence did not allow judgments regarding long-term use. Similarly, a 2011 systematic review of studies for non-cancer pain found that evidence of long-term efficacy is poor. One year later, a similar review reported poor evidence of long-term efficacy for morphine, tramadol, and oxycodone, and fair evidence for transdermal fentanyl (approved only for use for cancer pain).

285. On the contrary, evidence exists to show that opioid drugs are not effective to treat chronic pain and may worsen patients' health. A 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. Most notably, it stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids."[58] Another review of evidence relating to the use of opioids for chronic pain found that up to 22.9% of patients in opioid trials dropped out before the study began because of the intolerable effects of opioids, and that the evidence of pain relief over time was weak.

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[57] Nathaniel Katz, *Opioids: After Thousands of Years, Still Getting to Know You*, 23(4) Clin J. Pain 303 (2007); Roger Chou et al., *Research Gaps on Use of Opioids for Chronic Noncancer Pain*, 10(2) J. Pain 147 (2009).

[58] Andrea D. Furlan et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589 (2006). This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. Karen H. Seal, *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940 (2012).

286. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

287. As a pain specialist noted in an article titled *Are We Making Pain Patients Worse?*, "[O]pioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[59]

288. This is true both generally and for specific pain-related conditions. Studies of the use of opioids long-term for chronic lower back pain have been unable to demonstrate an improvement in patients' function. Conversely, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not help patients return to work or to physical activity. This is due partly to addiction and other side effects.

289. As many as 30% of patients who suffer from migraines have been prescribed opioids to treat their headaches. Users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users. A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

290. The lack of evidence for the efficacy of opioid use long-term has been well-documented nationally in the context of workers' compensation claims, where some of the most detailed data exists. Claims involving workers who take opioids are almost four times as likely to reach costs of over $100,000 than claims without opioids, as these patients suffer greater side

[59] Andrea Rubenstein, *Are we making pain patients worse?*, Sonoma Medicine (Fall 2009).

effects and are slower to return to work. Even adjusting for injury severity and self-reported pain score, taking an opioid for more than seven days and receiving more than one opioid prescription increased the risk that the patient would be on work disability one year later. A prescription for opioids, as the first treatment for a workplace injury, doubled the average length of the claim.

4. Defendants' Impact on the Perception and Prescribing of Opioids.

291. Before Defendants began the marketing campaign complained of herein, generally accepted standards of medical practice dictated that opioids should only be used short-term, for instance, for acute pain, pain relating to recovery from surgery, or for cancer or palliative care. In those instances, the risks of addiction are low or of little significance.

292. In 1986, the World Health Organization ("WHO") published an "analgesic ladder" for the treatment of cancer pain.[60] The WHO recommended treatment with over-the- counter or prescription acetaminophen or non-steroidal anti-inflammatory drugs ("NSAIDs") first, and then the use of unscheduled or combination opioids, and then stronger (Schedule II or III) opioids if pain persisted. The WHO ladder pertained only to the treatment of cancer pain and did not contemplate the use of narcotic opioids for chronic pain—because the use of opioids for chronic pain was not considered appropriate medical practice at the time.

293. Studies and articles from the 1970s and 1980s made the reasons to avoid opioids clear. Scientists observed negative outcomes from long-term opioid therapy in pain management programs: opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, or even prohibited, the use of opioid therapy for chronic pain.

[60] http://apps.who.int/iris/bitstream/10665/43944/1/9241561009_eng.pdf (accessed May 30, 2017)

294. In 1986, Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."[61]

295. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

> The traditional approach to chronic nonmalignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. *Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*[62]

296. According to Portenoy, these problems could constitute "compelling reasons to reject long term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain."[63]

297. For the reasons outlined by Dr. Portenoy, and in the words of one researcher from the Harvard Medical School, "it did not enter [doctors'] minds that there could be a significant

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[61] Russell K. Portenoy & Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986).
[62] Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt. 247 (1994) (emphasis added).
[63] *Id.*

number of chronic pain patients who were successfully managed with opioids."64 Defendants changed that perception.

B. Defendants Promoted Their Branded Products Through Direct Marketing to Prescribers and Consumers.

298. Defendants' direct marketing proceeded on two tracks, serving two related purposes. First, Defendants worked through branded and unbranded marketing to build confidence in long-term opioid use by overstating its benefits and downplaying its risks, thereby expanding the chronic pain market. In addition, Defendants worked through their own staffs of sales representatives, physician speakers whom those representatives recruited, and advertising in medical journals to claim their share of that broader market. Defendants directed all of this activity through carefully designed marketing plans that were based on extensive research into prescriber habits and the efficacy of particular sales approaches and messages.

1. Defendants Relied Upon Branded Advertisements.

299. Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the Journal of Pain and Clinical Journal of Pain, to journals with wider medical audiences, such as the Journal of the American Medical Association. Defendants' advertising budgets peaked in 2011, when they collectively spent more than $14 million on the medical journal advertising of opioids, nearly triple what they spent in 2001.

300. A number of these branded advertisements deceptively portrayed the benefits of opioid therapy for chronic pain. As just one example, a 2005 Purdue advertisement for OxyContin that ran in the *Journal of Pain* touted the drug as an "around-the-clock analgesic . . . for an

[64] Igor Kissin, *Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety?*, 6 J. Pain Research 513, 514 (2013) (quoting Loeser JD, *Five crises in pain management*, 20(1) Pain Clinical Updates 1-4 (2012).

extended period of time." The advertisement featured a man and boy fishing and proclaimed that "There Can Be Life With Relief." This depiction falsely implied that OxyContin provides both effective long-term pain relief and functional improvement, claims that, as described below, are unsubstantiated and contradicted in medical literature.

301. Defendants jumped on Purdue's bandwagon.

2. Defendants Relied Upon Their Sales Forces and Recruited Physician Speakers.

302. Defendants promoted the use of opioids for chronic pain through "detailers"— sales representatives who visited individual physicians and their staff in their offices—and small group speaker programs. By establishing close relationships with doctors, Defendants' sales representatives were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and to address individual prescribers' concerns about prescribing opioids for chronic pain. Representatives were trained on techniques to build these relationships.

303. Defendants developed sophisticated plans to select prescribers for sales visits based on their specialties and prescribing habits. In accordance with common industry practice, Defendants purchase and closely analyze prescription sales data from IMS Health. This data allows them to precisely track the rates of initial prescribing and renewal by individual doctors, which in turn allows them to target, tailor, and monitor the impact of their appeals.

304. Defendants, in particular, relied upon "influence mapping," *i.e.*, using decile rankings or similar breakdowns to identify the high-volume prescribers on whom detailing would have the greatest sales impact. Defendants also closely monitored doctors' prescribing after a sales representative's visit to allow them to refine their planning and messaging and to evaluate and compensate their detailers.

305. Defendants' sales representatives have visited hundreds of thousands of doctors, including thousands of visits to prescribers in Plaintiffs' geographic area, and as described herein, spread misinformation regarding the risks, benefits, and superiority of opioids for the treatment of chronic pain. This misinformation includes deceptive and unfair claims regarding the risks of opioids for chronic pain, particularly the risks of addiction, withdrawal, and high doses, as well as the benefits.

306. Each Defendant carefully trained its sales representatives to deliver company-approved messages designed to generate prescriptions of that company's drugs specifically, and opioids in general. Pharmaceutical companies exactingly direct and monitor their sales representatives—through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and other means—to ensure that individual detailers actually deliver the desired messages and do not veer off-script. Pharmaceutical companies likewise require their detailers to deploy sales aids reviewed, approved, and supplied by the company and forbid them to use, in industry parlance, "homemade bread"—*i.e.*, promotional materials not approved by the company's marketing and compliance departments. Sales representatives' adherence to their corporate training is typically included in their work agreements. Departing from their company's approved messaging can, and does, lead to severe consequences including termination of employment.

307. Besides carefully training their sales representatives, Defendants used surveys of physicians—conducted by third-party research firms—to assess how well their core messages came across to prescribers.

308. In addition to making sales calls, Defendants' detailers also identified doctors to serve, for payment, on Defendants' speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. Defendants almost always selected physicians who were "product loyalists," as they were sure to be asked whether they prescribe the drug themselves. Such

invitations are lucrative to the physicians selected for these bureaus; honorarium rates range from $800 to $2,000 per program, depending on the type of event, speaker training is typically compensated at $500 per hour.

309. These speaker programs and associated speaker trainings serve three purposes: they provide an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; a forum in which to further market to the speaker him or herself; and an opportunity to market to the speaker's peers. Defendants grade their speakers and future opportunities are based on speaking performance, post-program sales, and product usage. Defendants also track the prescribing of event attendees. It would make little sense for Defendants to devote significant resources to programs that did not increase their sales.

310. Like the sales representatives who select them, speakers are expected to stay "on message"—indeed, they agree in writing to follow the slide decks provided to them. Endo's speaker rules, for example, provide that "all slides must be presented in their entirety and without alterations . . . and in sequence." This is important because the FDA regards promotional talks as part of product labeling, and requires their submission for review. Speakers thus give the appearance of providing independent, unbiased presentations on opioids, when in fact they are presenting a script prepared by Defendants' marketing departments. Although these meal-based speaker events are more expensive to host, and typically have lower attendance than CMEs, they are subject to less professional scrutiny and thus afford Defendants greater freedom in the messages they present.

311. Defendants devoted massive resources to these direct sales contacts with prescribers.

312. Defendants have spent hundreds of millions of dollars promoting their opioids through their respective sales forces because they understand that detailers' sales pitches are

effective. Numerous studies indicate that marketing can and does impact doctors' prescribing habits,[65] and face-to-face detailing has the highest influence on intent to prescribe. Defendants could see this phenomenon at work not only in the aggregate, as their sales climbed with their promotional spending, but also at the level of individual prescribers whom they targeted for detailing, and who responded by prescribing more of Defendants' drugs.

3. Defendants Directed These Promotional Efforts Through Detailed Marketing Plans.

313. Defendants guided their efforts to expand opioid prescribing through comprehensive marketing and business plans for each drug. These documents, based on the companies' extensive market research, laid out ambitious plans to bring in new prescribers and increase overall prescribing of Defendants' opioids.

a. Targeting categories of prescribers

314. Defendants targeted, by zip codes and other local boundaries, individual health care providers for detailing. Defendants chose their targets based on the potential for persuading a provider to prescribe, ease of in-person access, and the likelihood of higher numbers of prescriptions at higher doses, with no correlation to demonstrated need or demand for opioid therapy, or to risk of abuse.

315. Collectively, Defendants' marketing plans evince dual strategies, which often operated parallel to one another. Defendants' sales representatives continued to focus their detailing efforts on pain specialists and anesthesiologists, the highest-volume prescribers of opioids and, as a group, more educated than other practitioners about opioids' risks and benefits. Seeking

[65] *See, e.g.,* Puneet Manchanda & Pradeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); Ian Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); *see also* Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

to develop market share and expand sales, however, Defendants also targeted increasing numbers and types of prescribers for marketing.

316. This expanded market of prescribers was, as a group, less informed about opioids and, as market research concluded, more susceptible to Defendants' marketing messages.

317. The expanded market also included internists and general practitioners who were low- to mid-volume prescribers.

b. Increasing "direct to consumer" marketing

318. Defendants knew that physicians were more likely to prescribe their branded medications when patients asked for those medications. Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused "education and support" materials. These took the form of pamphlets, videos, or other publications that patients could view in their physician's office, as well as employer and workers' compensation plan initiatives.

319. Defendants also knew that one of the largest obstacles to patients starting and remaining on their branded opioids—including by switching from a competitor's drug—was out-of-pocket cost. They recognized they could overcome this obstacle by providing patients financial assistance with their insurance co-payments, and each of the Defendants did so through vouchers and coupons distributed during detailing visits with prescribers.

c. Differentiating each brand

320. Purdue's OxyContin was the clear market leader in prescription opioid therapy, with 30% of the market for analgesic drugs in 2012. However, by 2010, Defendants had begun facing increasing pushback from the medical community and regulators based on the growing problems of opioid addiction and abuse. Both market conditions prompted Defendants to pursue product differentiation strategies—particularly an emphasis on their products being less subject to

diversion, abuse, and addiction—as a means of grabbing market share from Purdue and other competitors.

d. Moving beyond office visits

321. Defendants sought to reach additional prescribers by expanding beyond traditional sales calls and speaker events to new channels for their messages. For their sales forces, these included marketing to prescribers through voice mail, postcards, and email—so- called "e-detailing." Defendants also created new platforms for their speakers by implementing "peer to peer" programs such as teleconferences and webinars that were available to prescribers nationally. These programs allowed Defendants to use this more seemingly credible vehicle to market to, among other hard-to-reach audiences, prescribers at hospitals, academic centers, and other locations that limit or prohibit in-person detailing. Employing these new approaches, each Defendant relied heavily on speakers to promote its drugs.

4. Defendants Marketed Opioids in Plaintiffs' Geographic Area Using the Same Strategies and Messages They Employed Nationwide.

322. Defendants employed the same marketing plans and strategies and deployed the same messages in Plaintiffs' geographic area as they did nationwide.

323. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants' messages are accurately and consistently delivered across marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory. Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

324. Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees

who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide desks, and supervisors traveled with them periodically to check on both their performance and compliance.

325. As they did nationwide, Defendants extensively tracked the prescribing behavior of County-area health care providers and used that data to target their detailing and speaker- recruiting efforts. Top prescribers were profiled at Plaintiffs' geographic area, region, zip code, and sometimes facility levels, with information about their specialty, prescribing patterns (including product and dose), product loyalty and refill history. Providers' prescribing volume was ranked and sorted into deciles.

326. As described herein, misrepresentations and deceptions regarding the risks, benefits, and superiority of opioid use to treat chronic pain were part and parcel of Defendants' marketing campaigns in Plaintiffs' geographic area.

C. Defendants Used "Unbranded" Marketing to Evade Regulations and Consumer Protection Laws.

327. In addition to their direct marketing efforts, Defendants used unbranded, third- party marketing, which they deployed as part of their national marketing strategies for their branded drugs. Each Defendant executed these strategies through a network of third-party KOLs and Front Groups, with which it acted in concert by funding, assisting, encouraging, and directing their efforts. At the same time, Defendants exercised substantial control over the content of the messages third parties generated and disseminated and distributed certain of those materials themselves. As with their other marketing strategies, Defendants' unbranded marketing created, and relied upon, an appearance of independence and credibility that was undeserved but central to its effectiveness.

Unlike their direct promotional activities, Defendants' unbranded marketing allowed them to evade the oversight of federal regulators and gave them greater freedom to expand their deceptive messages.

1. Regulations Governing Branded Promotion Require that it Be Truthful, Balanced, and Supported by Substantial Evidence.

328. Drug companies that make, market, and distribute opioids are subject to generally applicable rules requiring truthful marketing of prescription drugs. A drug company's branded marketing, which identifies and promotes a specific drug, must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.[66] The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of drugs for their patients.

329. Further, the Federal Food, Drug, and Cosmetic Act ("FDCA") prohibits the sale in interstate commerce of drugs that are "misbranded." A drug is "misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular."[67] "Adequate directions for use" are directions "under which the layman can use a drug safely and for the purposes for which it is intended."[68] "Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional material.[69] "The term "accompanying" is interpreted broadly to include promotional materials—posters, websites, brochures, books, and the like—disseminated by or on behalf of the

[66] 21 U.S.C. § 352(a); 21 C.F.R. §§ 1.21(a), 202.1(e)(3), 202.1(e)(6).
[67] 21 U.S.C. §§ 352.
[68] 21 C.F.R. § 201.5.
[69] 21 U.S.C. § 321(m).

manufacturer of the drug.[70] Thus, Defendants' promotional materials are part of their drugs' labels and are required to be accurate, balanced, and not misleading.

330. Labeling is misleading if it is not based on substantial evidence, if it materially misrepresents the benefits of the drug, or if it omits material information about or minimizes the frequency or severity of a product's risks. "The most serious risks set forth in a product's labeling are generally material to ***any*** presentation of efficacy." The FDA notes that "[b]ecause people expect to see risk information, there is no reason for them to imagine that the product has important risks that have been omitted . . . especially if some risks are included."[71] Promotion that fails to present the most important risks of the drug as prominently as its benefits lacks fair balance and is therefore deceptive.

331. It is also illegal for drug companies to distribute materials that exclude contrary evidence or information about the drug's safety or efficacy or present conclusions that "clearly cannot be supported by the results of the study."[72] Further, drug companies must not make comparisons between their drugs and other drugs that represent or suggest that "a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience."[73]

332. While the FDA must approve a drug's label, it is the drug company's responsibility to ensure that the material in its label is accurate and complete and is updated to reflect any new information.[74] Promotional materials also must be submitted to the FDA when they are first used or disseminated. The FDA does not have to approve these materials in advance; if, upon review,

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[70] *See id.*
[71] FDA, *Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion*, May 2009, at 14.
[72] 21 C.F.R. § 99.101(a)(4).
[73] 21 C.F.R. § 202.1(e)(6)(ii).
[74] *See* 21 C.F.R. § 201.56 (providing general requirements for prescription drug labeling); *see also Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that a drug company bears responsibility for the content of its drug labels at all times); 21 C.F.R. § 314.70(c)(6) (iii)(A-C) (allowing manufacturers to make changes that "strengthen . . . a warning, precaution, or adverse reaction" or "strengthen a statement about drug abuse, dependence, psychological effect, or overdosage").

the FDA determines that materials marketing a drug are misleading, it can issue an untitled letter or warning letter. The FDA uses untitled letters for violations such as overstating the effectiveness of the drug or making claims without context or balanced information. Warning letters address promotions involving safety or health risks and indicate the FDA may take further enforcement action.

2. Defendants Deployed Front Groups and Doctors to Disseminate Unbranded Information on Their Behalf.

333. Drug companies market both directly and indirectly, using third party validators (such as scientists, physicians, patient or professional organizations) that appear to be independent and therefore more credible. The FDA has made clear that its promotional requirements apply to both forms of marketing:

> FDA's regulation of prescription drug product promotion extends both to promotional activities that are carried out by the firm itself, and to promotion conducted on the firm's behalf.
>
> . . . .
>
> Therefore, a firm is responsible for the content generated by its employees or any agents acting on behalf of the firm who promote the firm's product. For example, if an employee or agent of a firm, such as a medical science liaison or paid speaker (e.g., a key opinion leader) acting on the firm's behalf, comments on a third- party site about the firm's product, the firm is responsible for the content its employee or agent provides. A firm is also responsible for the content on a blogger's site if the blogger is acting on behalf of the firm.[75]

334. In addition to being carried out directly or through third parties, drug companies' promotional activity can be branded or unbranded; unbranded marketing refers not to a specific drug, but more generally to a disease state or treatment. By using unbranded communications, drug companies can sidestep the extensive regulatory framework governing branded communications.

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[75] FDA, *Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics*, January 2014, at 1, 4, http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm381352.pdf (accessed May 30, 2017).

335. Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing materials. These KOLs and Front Groups were important elements of Defendants' marketing plans, which specifically contemplated their use, because they seemed independent and therefore outside FDA oversight. Through unbranded materials, Defendants, with their own knowledge of the risks, benefits and advantages of opioids, presented information and instructions concerning opioids generally that were contrary to, or at best, inconsistent with information and instructions listed on Defendants' branded marketing materials and drug labels. Defendants did so knowing that unbranded materials typically are not submitted to or reviewed by the FDA.

336. Even where such unbranded messages were channeled through third-party vehicles, Defendants adopted these messages as their own when they cited to, edited, approved, and distributed such materials knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete. Unbranded brochures and other materials that are "disseminated by or on behalf of [the] manufacturer" constitute drug "labeling" that may not be false or misleading in any particular. *See* 21. C.F.R. 202.1(e)(7)(l)(2). [76] Defendants' sales representatives distributed third-party marketing material that was deceptive to Defendants' target audiences. Defendants are responsible for these materials.

337. Moreover, Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by these third parties, ensuring that Defendants were consistently aware of their content. By funding, directing, editing, and distributing these materials,

[76] This regulation provides: "Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and the references published . . . containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling, as defined in section 201(m) of the act." As labeling, such third party-created content distributed by a drug company may not be misleading and must meet the accuracy, substantiation, and fair balance requirements in the FDCA.

Defendants exercised control over their deceptive messages and acted in concert[77] with these third parties to fraudulently promote the use of opioids for the treatment of chronic pain.

338. For example, drug companies have been admonished for making functional claims in FDA-reviewed branded materials if there is no evidence for such claims. Thus, drug companies were put on notice that the FDA would not allow such claims in branded materials. Defendants instead created and disseminated these same unsupported claims—that opioids allow patients to sleep, return to work, or walk more easily—through *unbranded* marketing materials.

339. The third-party publications Defendants assisted in creating and distributing did not include the warnings and instructions mandated by their FDA-required drug labels and consistent with the risks and benefits known to Defendants. For example, these publications either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied that patients faced a serious risk of addiction.

340. By acting through third parties, Defendants were able to both avoid FDA scrutiny and give the false appearance that the messages reflected the views of independent third parties. Later, Defendants would cite to these sources as "independent" corroboration of their own statements. As one physician adviser to Defendants noted, third-party documents not only had greater credibility, but broader distribution as doctors did not "push back" at having materials from, for example, the non-profit American Pain Foundation ("APF") on display in their offices, as they might with first party, drug company pieces. Nevertheless, the independence of these materials was a ruse—Defendants were in close contact with these third parties, paid for and were aware of the misleading information they were disseminating about the use of opioids to treat chronic pain, and regularly helped them to tailor and distribute their misleading, pro-opioid messaging.

[77] As used in this Complaint, the allegation that Defendants "acted in concert" with third parties is intended to mean *both* that they conspired with these third parties to achieve some end and that they aided and abetted these third parties in the commission of acts necessary to achieve it.

341. As part of a strategic marketing scheme, Defendants spread and validated their deceptive messages through the following vehicles: (a) KOLs, who could be counted upon to write favorable journal articles and deliver supportive CMEs; (b) a body of biased and unsupported scientific literature; (c) treatment guidelines; (d) CMEs; (e) unbranded patient education materials; and (f) Front Group patient-advocacy and professional organizations, which exercised their influence both directly and through Defendant-controlled KOLs who served in leadership roles in those organizations.

a. Defendants' Use of KOLs

342. Defendants cultivated a small circle of doctors who, upon information and belief, were selected and sponsored by Defendants solely because they favored the aggressive treatment of chronic pain with opioids. Defendants' support helped these doctors become respected industry experts. In return, these doctors repaid Defendants by touting the benefits of opioids to treat chronic pain.

343. Pro-opioid doctors have been at the hub of Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. They have served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain (even while acknowledging the lack of evidence in support of that position) and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to exert control of each of these modalities through their KOLs.

344. In return, the KOLs' association with Defendants provided not only money, but prestige, recognition, research funding, and avenues to publish. This positioned them to exert even more influence in the medical community.

345. Although some KOLs initially may have advocated for more permissive opioid prescribing with honest intentions, Defendants cultivated and promoted only those KOLs who could be relied on to help broaden the chronic opioid therapy market. Defendants selected, funded, and elevated those doctors whose public positions were unequivocal and supportive of using opioids to treat chronic pain.[78] These doctors' professional reputations were then dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the drug companies.

346. Defendants cited and promoted favorable studies or articles by these KOLs. By contrast, Defendants did not support, acknowledge, or disseminate the publications of doctors critical of the use of chronic opioid therapy. Indeed, one prominent KOL sponsored by pharmaceutical companies, Russell Portenoy, stated that he was told by a drug company that research critical of opioids (and the doctors who published that research) would never obtain funding.

347. Defendants provided substantial opportunities for KOLs to participate in research studies on topics Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature. As described by Dr. Portenoy, drug companies would approach him with a study that was well underway and ask if he would serve as the study's author. Dr. Portenoy regularly agreed.

[78] Opioid-makers were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used KOLs in its effort to persuade the public and regulators that tobacco was not addictive or dangerous. For example, the tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in line with industry's views. He was dropped when he criticized low-tar cigarettes as potentially more dangerous, and later described himself as a pawn in the industry's campaign.

348. Defendants also paid KOLs to serve as consultants or on their advisory boards and give talks or present CMEs, typically over meals or at conferences.

349. These KOLs were carefully vetted to ensure that they were likely to remain on-message and supportive of a pharmaceutical industry agenda. One measure was a doctor's prior work for trusted Front Groups.

350. Defendants kept close tabs on the content of the misleading materials published by these KOLs. In many instances, they also scripted what these KOLs said—as they did with all their recruited speakers. The KOLs knew, or deliberately ignored, the misleading way in which they portrayed the use of opioids to treat chronic pain to patients and prescribers, but they continued to publish those misstatements to benefit themselves and Defendants, all the while causing harm to prescribers and patients within Plaintiffs' geographic area.

b. "Research" That Lacked Supporting Evidence

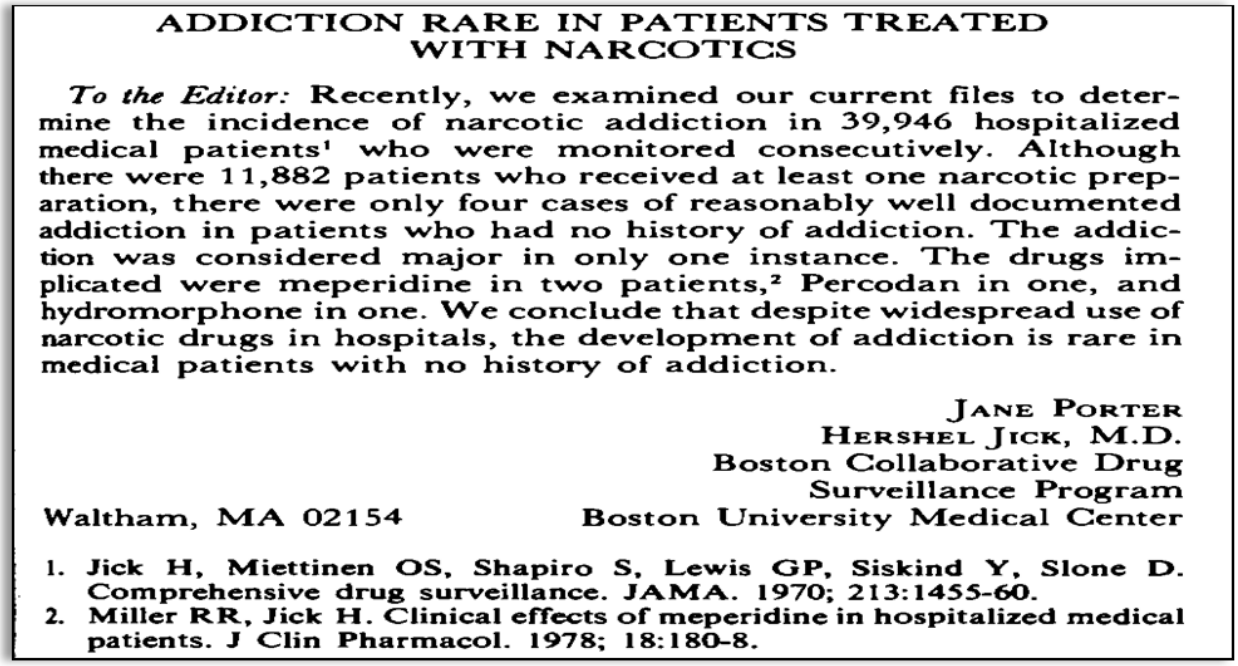
351. Rather than find a way to actually test the safety and efficacy of opioids for long-term use, Defendants led people to believe that they already had. Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to shape the perceptions of prescribers, patients and payors. This literature was, in fact, marketing material focused on persuading doctors and consumers that the benefits of long-term opioid use outweighed the risks.

352. To accomplish this, Defendants—sometimes through third-party consultants and/or advocacy organizations—commissioned, edited, and arranged for the placement of favorable articles in academic journals. Defendants' internal documents reveal plans to submit research papers and "studies" to long lists of journals, including back-up options and last resort, "fast-track" application journals, that they could use if the pending paper was rejected everywhere else.

353. Defendants coordinated the timing and publication of manuscripts, abstracts, posters/oral presentations, and educational materials in peer-reviewed journals and other publications to support the launch and sales of their drugs. The plans for these materials did not originate in the departments within the Defendant organizations that were responsible for research, development or any other area that would have specialized knowledge about the drugs and their effects on patients, but in Defendants' marketing departments and with Defendants' marketing and public relations consultants. Defendants often relied on "data on file" or presented posters, neither of which are subject to peer review. They also published their articles not through a competitive process, but in paid journal supplements, which allowed Defendants to publish, in nationally circulated journals, studies supportive of their drugs.

354. Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even where references distorted the significance or meaning of the underlying study. Most notably, Purdue promoted a 1980 reference in the well-respected *New England Journal of Medicine*: J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) *New Eng. J. Med.* 123 (1980) ("Porter-Jick Letter"). It is cited 856 times in Google Scholar, and 86 times since 2010. It also appears as a reference in two CME programs in 2012 sponsored by Purdue and Endo.[79] Defendants and those acting on their behalf fail to reveal that this "article" is actually a letter-to-the-editor, not a peer-reviewed study (or any kind of study at all). The Porter-Jick Letter, reproduced in full below, describes a review of the charts of hospitalized patients who had received opioids. (Because it was a 1980 study, standards of care almost certainly would have limited opioids to acute or end-of-life situations, not chronic pain.)

[79] AAPM, Safe Opioid Prescribing Course, February 25-26, 2012, sponsored by Purdue and Endo; "Chronic Pain Management and Opioid Use," October 11, 2012, sponsored by Purdue. Each CME is available for online credit, including to prescribers in Gennessee City.



ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

355. The Porter-Jick Letter notes that, when these patients' records were reviewed, it found almost no references to signs of addiction, though there is no indication that caregivers were instructed to assess or document signs of addiction. None of these serious limitations is disclosed when Defendants, or those acting on their behalf, cite the Porter-Jick Letter, typically as the sole scientific support for the proposition that opioids are rarely addictive, even when taken long-term. In fact, Dr. Jick later complained that his letter had been distorted and misused.

356. Defendants worked not only to create or elevate favorable studies in the literature, but to discredit or bury negative information. Defendants' studies and articles often targeted articles that contradicted Defendants' claims or raised concerns about chronic opioid therapy. In order to do so, Defendants—often with the help of third-party consultants—targeted a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

357. Defendants' strategies—first, to plant and promote supportive literature and then, to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that

contradicts those claims—are in dereliction of their legal obligations. The strategies were intended to, and did, knowingly and intentionally distort the truth regarding the risks, benefits, and superiority of opioids for chronic pain relief resulting in distorted prescribing patterns.

c. Treatment Guidelines

358. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are otherwise not experts, nor trained, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Furthermore, Endo's internal documents indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

i. *FSMB*

359. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

360. In 1998, the FSMB developed *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which FSMB admitted was produced "in collaboration with pharmaceutical companies."[80] The FSMB Guidelines taught not that opioids could be appropriate in limited cases or after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option. The FSMB

[80] FSMB, "Position of the FSMB in Support of Adoption of Pain Management Guidelines" (1998).

Guidelines failed to mention risks relating to respiratory depression and overdose, and they discussed addiction only in the sense that "inadequate understandings" of addiction can lead to "inadequate pain control."

361. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from the 2004 guidelines, *Responsible Opioid Prescribing*, also make these same claims. These guidelines were posted online and were available to and intended to reach physicians.

362. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers. The FSMB financed the distribution of *Responsible Opioid Prescribing* by its member boards by contracting with drug companies for bulk sales and distribution to sales representatives (for distribution to prescribing doctors).

363. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed to state medical boards (and through the boards, to practicing doctors), and the FSMB benefitted by earning approximately $250,000 in revenue and commissions from their sale. The FSMB website describes the book as the "leading continuing medication education (CME) activity for prescribers of opioid medications."

364. Drug companies relied on FSMB guidelines to convey the message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head—doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught that they would be punished instead if they failed to prescribe opioids to their patients with pain.

365. FSMB, more recently, has moderated its stance. Although the 2012 revision of *Responsible Opioid Prescribing* continued to teach that "pseudoaddiction" is real and that opioid addiction risk can be managed through risk screening, it no longer recommended chronic opioid

therapy as a first choice after the failure of over-the-counter medication and has heightened its addiction and risk warnings.

ii. *AAPM/APS Guidelines*

366. AAPM and the APS are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013 (with AAPM receiving over $2 million).

367. They issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain,* which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[81] The co-author of the statement, Dr. Haddox, was, at the time, a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement, which also formed the foundation of the FSMB Guidelines, remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.[82]

368. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines" or "Consensus Recommendations") and continued to recommend the use of opioids to treat chronic pain.[83] Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah.

369. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009

[81] Consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), *available at* http://opi.areastematicas.com/generalidades/OPIOIDES.DOLORCRONICO.pdf (accessed May 30, 2017).
[82] *Id.*
[83] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10(2) The Journal of Pain: Official Journal of the American Pain Society 113-130 (2009)

Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in Plaintiffs' geographic area during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

370. Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

iii. *American Geriatrics Society*

371. The American Geriatrics Society ("AGS"), a nonprofit organization serving health care professionals who work with the elderly, disseminated guidelines regarding the use of opioids for chronic pain in 2002 (The Management of Persistent Pain in Older Persons, hereinafter "2002 AGS Guidelines") and 2009 (Pharmacological Management of Persistent Pain in Older Persons, hereinafter "2009 AGS Guidelines"). The 2009 AGS Guidelines included the following recommendations: "All patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)," and "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."84 These recommendations, which continue to appear on AGS's website, are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited 278 times in Google Scholar since their 2009 publication.

372. AGS contracted with Endo, Purdue, and Janssen to disseminate the 2009 Guidelines, and to sponsor CMEs based on them. Defendants were aware of the content of the

[84] Pharmacological Management of Persistent Pain in Older Persons, 57 J. Am. Geriatrics Soc'y 1331, 1339, 1342 (2009), *available at* http://onlinelibrary.wiley.com/doi/10.1111/j.1526-4637.2009.00699.x/full (accessed May 30, 2017).

2009 Guidelines when they agreed to provide funding for these projects. The 2009 Guidelines were first published online on July 2, 2009. Internal AGS discussions in August 2009 reveal that it did not want to receive up-front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate the publication. However, by drafting the guidelines knowing that pharmaceutical company funding would be needed and allowing these companies to determine whether to provide support only after they had approved the message, AGS ceded significant control to these companies.

373. According to one news report, AGS has received $344,000 in funding from opioid makers since 2009.[85] The Institute of Medicine recommends that, to ensure an unbiased result, fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies.

iv. *Guidelines That Did Not Receive Defendants' Support*

374. The extent of Defendants' influence on treatment guidelines is demonstrated by the fact that independent guidelines—the authors of which did not accept drug company funding—reached very different conclusions. The 2012 Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it." ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with

[85] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee J. Sentinel, May 30, 2012.

serious health risks including multiple fatalities and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain." ASIPP recommends long-acting opioids in high doses only "in specific circumstances with severe intractable pain" and only when coupled with "continuous adherence monitoring, in well- selected populations, in conjunction with or after failure of other modalities of treatments with improvement in physical and functional status and minimal adverse effects."[86]

375. Similarly, the 2011 *Guidelines for the Chronic Use of Opioids*, issued by the American College of Occupational and Environmental Medicine, recommend against the "routine use of opioids in the management of patients with chronic pain," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence," while conceding there may be patients for whom opioid therapy is appropriate.[87]

376. The *Clinical Guidelines on Management of Opioid Therapy for Chronic Pain*, issued by the U.S. Department of Veterans Affairs ("VA") and Department of Defense ("DOD") in 2010, notes that their review:

> revealed the lack of solid evidence based research on the efficacy of long-term opioid therapy. Almost all of the randomized trials of opioids for chronic non-cancer pain were short-term efficacy studies. Critical research gaps . . . include: lack of effectiveness studies on long-term benefits and harms of opioids . . .; insufficient evidence to draw strong conclusions about optimal approaches to risk stratification . . .; lack of evidence on the utility of informed consent and opioid management plans . . .; and treatment of patients with chronic non-cancer pain at higher risk for drug abuse or misuse.[88]

d. Continuing Medical Education

[86] Laxmaiah Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment*, 15 Pain Physician (Special Issue) S1-S66; *Part 2 – Guidance*, 15 Pain Physician (Special Issue) S67-S116 (2012).
[87] *American College of Occupational and Environmental Medicine's Guidelines for the Chronic Use of Opioids*, (2011), *available at*: https://www.nhms.org/sites/default/files/Pdfs/ACOEM%202011-Chronic%20Pain%20Opioid%20.pdf (accessed May 30, 2017).
[88] Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010), *available at* http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full-er.pdf (accessed May 30, 2017).

377. CMEs are ongoing professional education programs provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations' conferences, online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs are typically delivered by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

378. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of focus and lack of specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to Defendants' deceptions.

379. In all, Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

380. The American Medical Association ("AMA") has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that

"[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the educational subject matter."[89]

381. Dozens of CMEs that were available to and attended or reviewed by doctors within Plaintiffs' geographical area during the relevant time period did not live up to the AMA's standards.

382. The influence of Defendants' funding on the content of these CMEs is clear. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded CME article on opioids versus another group who reviewed a non-industry-funded CME article. The industry-funded CME did not mention opioid-related death once; the non-industry-funded CME mentioned opioid-related death 26 times. Students who read the industry-funded article more frequently noted the impression that opioids were underused in treating chronic pain. The "take-aways" of those reading the non- industry-funded CME mentioned the risks of death and addiction much more frequently than the other group. Neither group could accurately identify whether the article they read was industry-funded, making clear the difficulty health care providers have in screening and accounting for source bias.[90]

383. By sponsoring CME programs presented by Front Groups like APF, AAPM, and others, Defendants could expect messages to be favorable to them, as these organizations were otherwise dependent on Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and Defendants measured the effects of CMEs on prescribers'

[89] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011), *available at* http://eo2.commpartners.com/users/ama/downloads/120328_Opinion_E-9_0115.pdf (accessed May 30, 2017).
[90] Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PharmedOut (June 25, 2010), *available at* pharmedout.galacticrealms.com/Fugh-BermanPrescriptionforConflict6-25-10.pdf.

views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

e. Unbranded Patient Education

384. Pharmaceutical industry marketing experts see patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats."[91] Evidence also demonstrates that physicians are willing to acquiesce to patient demands for a particular drug— even for opioids and for conditions for which they are not generally recommended.[92] An Actavis marketing plan, for example, noted that "[d]irect-to-consumer marketing affects prescribing decisions." Recognizing this fact, Defendants put their relationships with Front Groups to work to engage in largely unbranded patient education about opioid treatment for chronic pain.

385. The drug companies expect that they will recoup their investment in direct-to-consumer advertisements by capturing at least some of any additional prescriptions that result from patients "asking their doctor" about drugs that can treat their pain. Doctors also may review direct-to-consumer materials sales representatives give them to distribute to patients.

f. Defendants' Use of Front Groups

386. As noted above, Cephalon, Endo, Janssen, and Purdue entered into arrangements with numerous organizations to promote opioids. These organizations depend upon Defendants for significant funding and, in some cases, for their survival. They were involved not only in generating materials and programs for doctors and patients that supported chronic opioid therapy, but also in assisting Defendants' marketing in other ways—for example, responding to negative

[91] Kanika Johar, *An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices*, 76 Albany L. Rev. 299, 308 (2013).

[92] Prescribers often accede to patient requests. According to one study, nearly 20% of sciatica patients requesting oxycodone would receive a prescription for it, compared with 1% making no request. More than half of patients requesting a strong opioid received one. J.B. McKinlay et al., *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).

articles and advocating against regulatory changes that would constrain opioid prescribing. They developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on use of opioids to treat chronic pain. Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages.

387. Several representative examples of such Front Groups are highlighted below, but there are others, too, such as APS, AGS, FSMB, American Chronic Pain Association ("ACPA"), AAPM, American Society of Pain Educators ("ASPE"), NPF, and PPSG.

i. *American Pain Foundation*

388. The most prominent of Front Groups was APF, which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012.

389. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes—including death—among returning soldiers. APF also engaged in a significant multimedia campaign—through radio, television and the internet—to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach residents in Plaintiffs' geographic area.

390. In addition to Perry Fine, Russell Portenoy, and Scott Fishman, who served on APF's Board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

391. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from pharmaceutical companies to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

392. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Defendants' promotional activities, including Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. As laid out below, APF functioned largely as an advocate for the interests of Defendants, not patients. Indeed, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

393. In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications APF could pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

394. APF assisted in other marketing projects for drug companies. One project funded by another drug company—*APF Reporter's Guide: Covering Pain and Its Management* (2008)[93]—recycled text that was originally created as part of the company's training document.

395. The same drug company made general grants, but even then, it directed how APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medications generally, the company representative responded, "I provided an advocacy grant to APF this year—this would be a very good issue on which to use some of that. How does that work?"

396. The close relationship between APF and the drug company was not unique. APF's clear lack of independence—in its finances, management, and mission—and its willingness to allow Defendants to control its activities and messages, support an inference that each Defendant that worked with APF was able to exercise editorial control over its publications.

397. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party and Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[94]

ii. *The American Academy of Pain Medicine*

398. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted

[93] https://assets.documentcloud.org/documents/277606/apf-reporters-guide.pdf (accessed May 30, 2017).
[94] http://www.painfoundation.org (last visited May 30, 2017).

medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy.

399. AAPM has received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintains a corporate relations council, whose members pay $25,000 per year (on top of other funding) to participate. The benefits include allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors.

400. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings.

401. The conferences sponsored by AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[95]

402. AAPM's staff understood that they and their industry funders were engaged in a common practice. Defendants were able to influence AAPM through both their significant and regular funding, and the leadership of pro-opioid KOLs within the organization.

3. Defendants Acted in Concert with KOLs and Front Groups in the Creation, Promotion, and Control of Unbranded Marketing.

403. Like cigarette manufacturers, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Defendants worked with each other and with the

[95] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), http://www.medscape.org/viewarticle/500829 (accessed May 30, 2017).

Front Groups and KOLs they funded and directed to carry out a common scheme to deceptively present the risks, benefits, and superiority of opioids to treat chronic pain.

404. Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the very same language and format to disseminate the same deceptive messages. These KOLs have worked reciprocally with Defendants to promote misleading messaging regarding the appropriate use of opioids to treat chronic pain. Although participants knew this information was false and misleading, these misstatements were nevertheless disseminated to prescribers and patients in Plaintiffs' geographic area.

405. One vehicle for their collective collaboration was Pain Care Forum ("PCF"). PCF began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and to "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the Forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

406. PCF is comprised of representatives from opioid manufacturers and distributors; doctors and nurses in the field of pain care; professional organizations (*e.g.*, American Academy of Pain Management, APS, and American Society of Pain Educators); patient advocacy groups (*e.g.*, APF and ACPA); and other like-minded organizations (*e.g.*, FSMB and Wisconsin Pain & Policy Studies Group), almost all of which received substantial funding from Defendants.

407. PCF, for example, developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients.[96] This was critical as a

[96] The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

REMS that went too far in narrowing the uses or benefits, or highlighting the risks of chronic opioid therapy, would deflate Defendants' marketing efforts. The recommendations—drafted by Will Rowe of APF—claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers."[97] Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, and not undermine, their deceptive marketing of opioids for chronic pain.

4. Defendants Targeted Vulnerable and Lucrative Populations.

a. The Elderly

408. Elderly patients taking opioids have been found to be exposed to elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression, which, as Defendants acknowledge in their labels (but not in their marketing), occurs more frequently in elderly patients. A 2010 paper in the Archives of Internal Medicine reported that elderly patients who used opioids had a significantly higher rate of death, heart attacks, and strokes than users of NSAIDs. Defendants' targeted marketing to the elderly and the absence of cautionary language in their promotional materials flies in the face of scientific evidence and their own labels and creates a heightened risk of serious injury to elderly patients.

409. Defendants also promoted the notion—also without adequate scientific foundation—that the elderly are particularly unlikely to become addicted to opioids.

410. Defendants' efforts have paid off. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59.

[97] Defendants also agreed that short-acting opioids should also be included in REMS as not to disadvantage the long-acting, branded drugs.

b. Veterans

411. Veterans, too, are suffering greatly from the effects of Defendants' targeted marketing. A 2008 survey showed that prescription drug abuse among military personnel doubled from 2002 to 2005, and then nearly tripled again over the next three years. In 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills—four times as many as they did in 2001. Further, one-third of veterans prescribed opioids as of 2012 remained on take-home opioids for more than 90 days. Although many of these veterans are returning from service with traumatic injuries, the increase in opioid prescribing is disproportionate to the population and, in far too many cases, unsuited for their treatment. Among former service members receiving VA services nationally in a single year (2005), 1,013 had died of accidental drug overdoses—double the rate of the civilian population.

412. Plaintiffs have a substantial population of veterans who must cope with the consequences of overprescribing opioids.

413. Opioids are particularly dangerous to veterans. According to a study published in the 2013 Journal of American Medicine, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental injuries; 40% of veterans with post-traumatic stress disorder received opioids and benzodiazepines (anti-anxiety drugs) that, when mixed with alcohol, can cause respiratory depression and death. According to a VA Office of Inspector General Report, despite the risks, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines.[98] Again, as with elderly patients, Defendants both purposefully sought to increase opioid prescribing to this vulnerable group and omitted from their promotional materials the known, serious risks opioids pose to them.

[98] https://www.va.gov/oig/pubs/VAOIG-14-00895-163.pdf (accessed May 30, 2017).

414. *Exit Wounds*, a 2009 publication sponsored by Purdue, distributed by APF with grants from Janssen and Endo, and written as a personal narrative of one veteran, describes opioids as "underused" and the "gold standard of pain medications" and fails to disclose the risk of addiction, overdose, or injury. It notes that opioid medications "increase a person's level of functioning" and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications." The book also asserts that "[d]enying a person opioid pain medication because he or she has a history of substance abuse or addiction is contrary to the model guidelines for prescribing opioids, published by the U.S. Federation of State Medical Boards." As laid out above, the FSMB itself received support from Defendants during the time it created and published its guidelines.

415. *Exit Wounds* minimizes the risks of chronic opioid therapy and does not disclose the risk that opioids may have fatal interactions with benzodiazepines, which were taken by a significant number of veterans.[99] It is not the unbiased narrative of a returning war veteran. The American Pain Foundation's name is prominently marked on the book's spine. Dr. Scott Fishman, then-chair of the APF, wrote the book's preface, which touted the APF as "an organization that raises public awareness, provides education, promotes research, and advocates for improved access to effective pain management – answering the unmet needs of our active military and veterans in pain."

416. The deceptive nature of *Exit Wounds* is obvious in comparing it to guidance on opioids published by the VA and DOD in 2010 and 2011. The VA's *Taking Opioids Responsibly* describes opioids as "dangerous." It cautions against taking extra doses and mentions the risk of overdose and the dangers of interactions with alcohol. The list of side effects from opioids includes

[99] FDA guidance states that materials designed to target a particular audience should disclose risks particular to that audience. *See* FDA Notice, Guidance for Industry, "Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs," August 6, 2015.

decreased hormones, sleep apnea, hyperalgesia, addiction, immune system changes, birth defects and death—none of which is disclosed in *Exit Wounds*.

D. Why Defendants' Marketing Messages Are Misleading and Unfair

417. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The Defendants and their allies had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers.

418. Defendants' marketing of opioids for long-term use to treat chronic pain, both directly and with and through third parties, included information that was false, misleading, contrary to credible scientific evidence and their own labels, and lacked balance and substantiation. Their marketing materials omitted material information about the risks of opioids and overstated their benefits. Moreover, Defendants inaccurately suggested that chronic opioid therapy was supported by evidence and failed to disclose the lack of evidence in support of treating chronic pain with opioids.

419. There are seven primary misleading and unfounded representations. Defendants and the third parties with which they teamed:

- misrepresented that opioids improve function;
- concealed the link between long-term use of opioids and addiction;
- misrepresented that addiction risk can be managed;
- masked the signs of addiction by calling them "pseudoaddiction";
- falsely claimed withdrawal is easily managed;
- misrepresented or omitted the greater dangers from higher doses of opioids; and

- deceptively minimized the adverse effects of opioids and overstated the risks of NSAIDs.

420. Exacerbating each of these misrepresentations and deceptions was the collective effort of Defendants and third parties to hide from the medical community the fact that the FDA "is not aware of adequate and well-controlled studies of opioid use longer than 12 weeks."[100]

1. Defendants and Their Third-Party Allies Misrepresented that Opioids Improve Function

421. Each of the following materials was created with the expectation that, by instructing patients and prescribers that opioids would improve patients' function and quality of life, patients would demand opioids and doctors would prescribe them. These claims also encouraged doctors to continue opioid therapy in the belief that failure to improve pain, function, or quality of life, could be overcome by increasing doses or prescribing supplemental short-acting opioids to take on an as-needed basis for breakthrough pain.

422. However, not only is there no evidence of improvement in long-term functioning, a 2006 study-of-studies found that "[f]or functional outcomes . . . other analgesics were significantly more effective than were opioids."[101] Studies of the use of opioids in chronic conditions for which they are commonly prescribed, such as low back pain, corroborate this conclusion and have failed to demonstrate an improvement in patients' function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not cause patients to return to work or physical activity.[102] Indeed, one Defendant's own internal marketing plans

[100] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).
[101] Andrea D. Furlan et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589-1594 (2006). This study revealed that efficacy studies do not typically include data on opioid addiction, such that, if anything, the data overstate effectiveness.
[102] Moreover, users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users. They also were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

characterized functional improvement claims as "aspirational." Another acknowledged in 2012 that "[s]ignificant investment in clinical data [was] needed" to establish opioids' effect on mitigating quality of life issues, like social isolation.

423. The long-term use of opioids carries a host of serious side effects, including addiction, mental clouding and confusion, sleepiness, hyperalgesia, and immune-system and hormonal dysfunction that degrade, rather than improve, patients' ability to function. Defendants often omitted these adverse effects as well as certain risks of drug interactions from their publications.

2. Defendants and Their Third-Party Allies Concealed the Truth About the Risk of Addiction from Long-Term Opioid Use

424. The fraudulent representation that opioids are rarely addictive is central to Defendants' scheme. To reach chronic pain patients Defendants, and the Front Groups and KOLs that they directed, assisted, and collaborated with, had to overcome doctors' legitimate fears that opioids would addict their patients. The risk of addiction is an extremely weighty risk—condemning patients to, among other things, dependence, compulsive use, haziness, a lifetime of battling relapse, and a dramatically heightened risk of serious injury or death. But for Defendants' campaign to convince doctors otherwise, finding benefits from opioid use for common chronic pain conditions sufficient to justify that risk would have, and previously had, posed a nearly insurmountable challenge.

425. Through their well-funded, comprehensive marketing efforts, Defendants and their KOLs and Front Groups were able to change prescriber perceptions despite the well-settled historical understanding and clear evidence that opioids taken long-term are often addictive. Defendants and their third-party partners: (a) brazenly maintained that the risk of addiction for patients who take opioids long-term was low; and (b) omitted the risk of addiction and abuse from

the list of adverse outcomes associated with chronic opioid use, even though the frequency and magnitude of the risk—and Defendants' own labels—compelled disclosure.

426. Further, in addition to falsely claiming opioids had low addiction risk or omitting disclosure of the risk of addiction altogether, Defendants employed language that conveyed to prescribers that the drugs had lower potential for abuse and addiction. Further, in addition to making outright misrepresentations about the risk of addiction, or failing to disclose that serious risk at all, Defendants used code words that conveyed to prescribers that their opioid was less prone to abuse and addiction.

427. Each of the following was created with the expectation that, by instructing patients and prescribers that addiction rates are low and that addiction is unlikely when opioids are prescribed for pain, doctors would prescribe opioids to more patients. For example, one publication sponsored exclusively by Purdue—APF's 2011 *A Policymaker's Guide to Understanding Pain & Its Management*—claimed that opioids are not prescribed often enough because of "misconceptions about opioid addiction."[103]

428. Acting directly or with and through third parties, each of the Defendants claimed that the potential for addiction from its drugs was relatively small, or non-existent, even though there was no scientific evidence to support those claims, and the available research contradicted them. A recent literature survey found that while ranges of "problematic use" of opioids ranged from <1% to 81%,[104] abuse averages between 21% and 29% and addiction between 8% and 12%.[105] These estimates are well in line with Purdue's own studies, showing that between 8% and 13% of OxyContin patients became addicted, but on which Purdue chose not to rely, instead citing the Porter-Jick letter.

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[103] http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (accessed May 30, 2017).
[104] Cited for the low end of that range was the 1980 Porter-Jick letter in the *New England Journal of Medicine.*
[105] Kevin Vowels et al., *Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis*, 156 PAIN 569-76 (April 2015).

429. The FDA has found that 20% of opioid patients use two or more pharmacies, 26% obtain opioids from two or more prescribers, and 16.5% seek early refills—all potential "red flags" for abuse or addiction.[106] The FDA in fact has ordered manufacturers of long-acting opioids to "[c]onduct one or more studies to provide quantitative estimates of the serious risks of misuse, abuse, addiction, overdose and death associated with long-term use of opioid analgesics for management of chronic pain," in recognition of the fact that it found "high rates of addiction" in the medical literature.[107]

430. Of course, the significant (and growing) incidence of abuse, misuse, and addiction to opioids is also powerful evidence that Defendants' statements regarding the low risk of addiction were, and are, untrue. This was well-known to Defendants who had access to sales data and reports, adverse event reports, federal abuse and addiction-related surveillance data, and other sources that demonstrated the widening epidemic of opioid abuse and addiction.

431. Acting directly or through and with third parties, each of the Defendants claimed that the potential for addiction even from long-term use of its drugs was relatively small, or non-existent, despite the fact that the contention was false and there was no scientific evidence to support it. In addition to denying or minimizing the risk of addiction and abuse generally, Defendants also falsely claimed that their particular drugs were safer, less addictive, and less likely to be abused or diverted than their competitors' or predecessor drugs. In making these claims, Defendants said or implied that because their drug had a "steady-state" and did not produce peaks and valleys, which cause drug-seeking behavior—either to obtain the high or avoid the low—it was

[106] Len Paulozzi, M.D., "Abuse of Marketed Analgesics and Its Contribution to the National Problem of Drug Abuse," *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndLifeSupportDrugsAdvisoryCommittee/UCM233244.pdf (accessed May 30, 2017).

[107] September 10, 2013 letter from Bob Rappaport, M.D., to NDA applicants of ER/LA opioid analgesics, *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf (accessed May 30, 2017).; Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

less likely to be abused or addicting. Defendants had no evidence to support any of these claims, which, by FDA regulation, must be based on head-to-head trials;[108] the claims also were false and misleading in that they misrepresented the risks of both the particular drug and opioids as a class.

432. Further, rather than honestly disclose the risk of addiction, Defendants, and the third parties they directed and assisted and whose materials they distributed, attempted to portray those who were concerned about addiction as unfairly denying treatment to needy patients. To increase pressure on doctors to prescribe chronic opioid therapy, Defendants turned the tables; it was doctors who fail to treat their patients' chronic pains with opioids—not doctors who cause their patients to become addicted to opioids—who are failing their patients (and subject to discipline). Defendants and their third-party allies claimed that purportedly overblown worries about addiction cause pain to be under-treated and opioids to be over-regulated and under-prescribed. This mantra of under-treated pain and under-used drugs reinforced Defendants' messages that the risks of addiction and abuse were not significant and were overblown.

3. Defendants and Their Third-Party Allies Misrepresented that Addiction Risk Can Be Avoided or Managed.

433. To this day, defendants each continue to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted. Presumably only to explain why doctors encounter so many patients addicted to opioids, Defendants and their third-party allies have come to admit that some patients could become addicted, but that doctors can avoid or manage that risk by using screening tools or questionnaires. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse) so that doctors can more closely monitor patients at greater risk of addiction.

[108] *See Guidance for Industry*, "Abuse-Deterrent Opioids—Evaluation and Labeling," April 2015 (describing requirements for premarket and postmarket studies).

434. There are three fundamental flaws in these assurances that doctors can identify and manage the risk of addiction. First, there is no reliable scientific evidence that screening works to accurately predict risk or reduce rates of addiction. Second, there is no reliable scientific evidence that high-risk or addicted patients can take opioids long-term without triggering addiction, even with enhanced monitoring and precautions. Third, there is no reliable scientific evidence that patients without these red flags are necessarily free of addiction risk.

435. Addiction is difficult to predict on a patient-by-patient basis, and there are no reliable, validated tools to do so. A recent Evidence Report by the Agency for Healthcare Research and Quality ("AHRQ"), which "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain" identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse- deterrent formulations on outcomes related to overdose, addiction, abuse or misuse."[109] Furthermore, attempts to treat high-risk patients, such as those who have a documented predisposition to substance abuse, by resorting to patient contracts, more frequent refills, or urine drug screening are not proven to work in the real world, if busy doctors even in fact attempt them.

436. Most disturbingly, despite the widespread use of screening tools, patients with past substance use disorders—which every tool rates as a risk factor—receive, on average, higher doses of opioids.

4. Defendants and Their Third-Party Allies Created Confusion By Promoting the Misleading Term "Pseudoaddiction."

[109] *The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain*, Agency for Healthcare Res. & Quality (September 19, 2014).

437. Defendants and their third-party allies developed and disseminated each of the following misrepresentations with the intent and expectation that, by instructing patients and prescribers that signs of addiction are actually the product of untreated pain, doctors would prescribe opioids to more patients and continue to prescribe them, and patients would continue to use opioids despite signs that the patient was addicted. The concept of "pseudoaddiction" was coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, who consulted for Cephalon, Endo, Janssen, and Purdue. Much of the same language appears in other Defendants' treatment of this issue, highlighting the contrast between "undertreated pain" and "true addiction," as if patients could not experience both. As KOL Dr. Lynn Webster wrote: "[Pseudoaddiction] obviously became too much of an excuse to give patients more medication... It lead us down a path that caused harm. It is already something we are debunking as a concept."[110]

5. Defendants and Their Third-Party Allies Claimed Withdrawal is Simply Managed.

438. Defendants and their third-party allies promoted the false and misleading messages below with the intent and expectation that, by misrepresenting the difficulty of withdrawing from opioids, prescribers and patients would be more likely to start chronic opioid therapy and would fail to recognize the actual risk of addiction.

439. In an effort to underplay the risk and impact of addiction, Defendants and their third-party allies frequently claim that, while patients become "physically" dependent on opioids, physical dependence can be addressed by gradually tapering patients' doses to avoid the adverse effects of withdrawal. They fail to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—effects that also make it less likely that patients will be able to stop using the drugs.

[110] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee Wisc. J. Sentinel (Feb.19, 2012).

440. In reality, withdrawal is prevalent in patients after more than a few weeks of therapy. Common symptoms of withdrawal include severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, and pain. Some symptoms may persist for months, or even years, after a complete withdrawal from opioids, depending on how long the patient had been using opioids. Withdrawal symptoms trigger a feedback loop that drives patients to seek opioids, contributing to addiction.

6. Defendants and Their Third-Party Allies Misrepresented that Increased Doses Pose No Significant Additional Risks.

441. Each of the following misrepresentations was created with the intent and expectation that, by misrepresenting and failing to disclose the known risks of high dose opioids, prescribers and patients would be more likely to continue to prescribe and use opioids, even when they were not effective in reducing patients' pain, and not to discontinue opioids even when tolerance required them to reach even higher doses.

442. Defendants and their third-party allies claimed that patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were "frighteningly high," suggesting that patients would eventually reach a stable, effective dose. Each of Defendants' claims also omitted warnings of increased adverse effects that occur at higher doses, and misleadingly suggested that there was no greater risk to higher dose opioid therapy.

443. These claims are false. Patients receiving high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer an overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects. Accordingly, the practice of continuously escalating doses to

match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended. The FDA has itself acknowledged that available data suggest a relationship between increased doses and the risk of adverse effects. Moreover, it is harder for patients to terminate use of higher-dose opioids without severe withdrawal effects, which contributes to a cycle of continued use, even when the drugs provide no pain relief and are causing harm—the signs of addiction.

7. Defendants and Their Third-Party Allies Deceptively Omitted or Minimized Adverse Effects of Opioids and Overstated the Risks of Alternative Forms of Pain Treatment.

444. Each of the following misrepresentations was created with the intent and expectation that, by omitting the known, serious risks of chronic opioid therapy, including the risks of addiction, abuse, overdose, and death, and emphasizing or exaggerating risks of competing products, prescribers and patients would be more likely to choose opioids. Defendants and their third-party allies routinely ignored the risks of chronic opioid therapy. These include (beyond the risks associated with misuse, abuse, and addiction): hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;" [111] hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (disorders frequently coexisting with chronic pain conditions).[112]

[111] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[112] Several of these risks do appear in the FDA-mandated warnings. *See, e.g.*, the August 13, 2015 OxyContin Label, Section 6.2, identifying adverse reactions including: "abuse, addiction … death, … hyperalgesia, hypogonadism . . . mood altered . . . overdose, palpitations (in the context of withdrawal), seizures, suicidal attempt, suicidal ideation, syndrome of inappropriate antidiuretic hormone secretion, and urticaria [hives]."

445. Despite these serious risks, Defendants asserted, or implied, that opioids were appropriate first-line treatments and safer than alternative treatments, including NSAIDs such as ibuprofen (Advil, Motrin) or naproxen (Aleve). While NSAIDs can pose significant gastrointestinal, renal, and cardiac risks, particularly for elderly patients, Defendants' exaggerated descriptions of those risks were deceptive in themselves, and also made their omissions regarding the risks of opioids all the more striking and misleading. Defendants and their third-party allies described over-the-counter NSAIDs as life-threatening and falsely asserted that they were responsible for 10,000-20,000 deaths annually (more than opioids), when in reality the number is closer to 3,200. This description of NSAIDs starkly contrasted with their representation of opioids, for which the listed risks were nausea, constipation, and sleepiness (but not addiction, overdose, or death). Compared with NSAIDs, opioids are responsible for roughly four times as many fatalities annually.

446. As with the preceding misrepresentations, Defendants' false and misleading claims regarding the comparative risks of NSAIDs and opioids had the effect of shifting the balance of opioids' risks and purported benefits. While opioid prescriptions have exploded over the past two decades, the use of NSAIDs has declined during that same time.

E. Each Defendant Engaged in Deceptive Marketing, Both Branded and Unbranded, that Targeted and Reached County Prescribers.

447. Defendants—and the Front Groups and KOLs who depended on and worked alongside them—were able to affect a sea change in medical opinion in favor of accepting opioids as a medically necessary long-term treatment for chronic pain. As set forth below, each Defendant contributed to that result through a combination of both direct marketing efforts and third-party marketing efforts over which that Defendant exercised editorial control. These deceptive and misleading statements were directed to, and reached, prescribers and patients in Plaintiffs'

geographic area, with the intent of distorting their views on the risks, benefits, and superiority of opioids for treatment of chronic pain.

448. Defendants engaged in their deceptive marketing campaign, both nationwide and in Plaintiffs' geographic area, using a number of strategies. Defendants trained their sales forces and recruited physician speakers to deliver these deceptive messages and omissions, and they in turn conveyed them to prescribers. Defendants also broadly disseminated promotional messages and materials, both by delivering them personally to doctors during detailing visits and by mailing deceptive advertisements directly to prescribers. Because they are disseminated by Defendant drug manufacturers and relate to Defendants' drugs, these materials are considered "labeling" within the meaning of 21 C.F.R. § 1.3(a), which means Defendants are liable for their content.

449. Each of the misrepresentations received by these doctors constitutes an integral piece of a centrally directed marketing strategy to change medical perceptions regarding the use of opioids to treat chronic pain. Defendants were aware of each of these misrepresentations, and Defendants approved of them and oversaw their dissemination at the national, corporate level.

F. The Result of Defendants' Fraudulent Scheme

450. Through their direct promotional efforts, along with those of the third-party Front Groups and KOLs they assisted and controlled, and whose seemingly objective materials they distributed, Defendants accomplished exactly what they set out to do: change the institutional and public perception of the risk-benefit assessments and standard of care for treating patients with chronic pain. As a result, doctors in Plaintiffs' geographic area began prescribing opioids long-term to treat chronic pain—something most would never have considered prior to Defendants' campaign.

451. But for the misleading information disseminated by Defendants, doctors would not, in most instances, have prescribed opioids as medically necessary or reasonably required to address chronic pain.

1. Defendants' Fraudulent and Deceptive Marketing of Opioids Directly Caused Harm to Plaintiffs.

452. In the first instance, Plaintiffs were damaged directly, through its payments of false claims for chronic opioid therapy by (a) partially funding a medical insurance plan for its employees and (b) its workers' compensation program.

453. Defendants' marketing of opioids caused health care providers to prescribe, and Plaintiffs' geographic area, through partially funding a medical insurance plan for its employees and its workers' compensation program, to pay for prescriptions of opioids to treat chronic pain. Because of Defendants' unbranded marketing, health care providers wrote, and Plaintiffs paid for prescriptions of opioids for chronic pain that were filled not only with their drugs, but with opioids sold by other manufacturers. All of these prescriptions were caused by Defendants' fraudulent marketing and therefore all of them constitute false claims. Because, as laid out below, Plaintiffs are obligated to cover medically necessary and reasonably required care, it had no choice but to pay for these false and fraudulent claims.

454. The fact that Plaintiffs would pay for these ineligible prescriptions was both the foreseeable and intended consequence of Defendants' fraudulent marketing scheme. Defendants set out to change the medical and general consensus supporting chronic opioid therapy with the intention of encouraging doctors to prescribe, and government payors such as Plaintiffs, to pay for long-term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

a. Increase in Opioid Prescribing Nationally

455. Defendants' scheme to change the medical consensus regarding opioid therapy for chronic pain was greatly successful. During the year 2000, outpatient retail pharmacies filled 174 million prescriptions for opioids nationwide, rising to 257 million in 2009.[113]

456. Opioid prescriptions increased even as the percentage of patients visiting doctors for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline of NSAID use.[114]

457. Approximately 20% of the population between the ages of 30 and 44 and nearly 30% of the population over 45 have used opioids. Indeed, "[o]pioids are the most common means of treatment for chronic pain."[115] From 1980 to 2000, opioid prescriptions for chronic pain visits doubled. This resulted not from an epidemic of pain, but an epidemic of prescribing. A study of 7.8 million doctor visits found that prescribing for pain increased by 73% between 2000 and 2010—even though the number of office visits in which patients complained of pain did not change and prescribing of non-opioid pain medications ***decreased***. For back pain alone—one of the most common chronic pain conditions—the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined and referrals to physical therapy remained steady—and climbing.

458. This increase corresponds with, and was caused by, Defendants' massive marketing push.

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[113] Office of National Drug Control Policy, *2011 Prescription Drug Abuse Prevention Plan*, Whitehouse.gov, (no longer available on whitehouse.gov), https://obamawhitehouse.archives.gov/ondcp/prescription-drug-abuse1 (accessed May 30, 2017).

[114] Matthew Daubresse et al., *Ambulatory* Diagnosis *and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care 870 (2013).

[115] Deborah Grady et al., *Opioids for Chronic Pain*, 171(16) Arch. Intern. Med. 1426 (2011).

459. Defendants' opioid detailing visits to individual doctors made up the largest component of this spending, with total detailing expenditures more than doubling between 2000 and 2014 to $168 million annually.

b. Plaintiffs' Increased Spending on Opioids

460. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiffs have been required to spend millions of dollars each year in its efforts to combat the public nuisance created by Defendants' deceptive marketing campaign. Plaintiff has incurred, and continues to incur, costs related to opioid addiction and abuse, including, but not limited to, health care costs, criminal justice and victimization costs, social costs, and lost productivity costs. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiffs and their residents.

i. *Defendants' Misrepresentations Were Material*

461. Defendants' misrepresentations were material to, and influenced, Plaintiffs' decisions to pay claims for opioids for chronic pain (and, therefore, to bear its consequential costs in treating overdose, addiction, and other side effects of opioid use). In the first instance, Plaintiffs would not have been presented with, or paid, claims for opioids that would not have been written but for Defendants' fraudulent and deceptive marketing. Second, Plaintiffs have demonstrated that Defendants' marketing is material by taking further steps to ensure that the opioids are only prescribed and covered when medically necessary or reasonably required.

462. As laid out above, Defendants' misrepresentations related to Plaintiffs' requirement that medical treatments be medically necessary or reasonably required – a condition of payment for any medical treatment under Plaintiffs' health plans and workers' compensation program. But for Defendants' fraudulent and deceptive marketing, prescribers would have accurately understood the risks and benefits of opioids and would not have prescribed opioids where not medically necessary

or reasonably required to treat chronic pain. Misrepresentations as to, for example, whether patients were likely to become addicted to the drug, would be able to resume life activities, and would experience long-term relief were not minor or insubstantial matters, but the core of prescribers' decision-making.

463. It is Plaintiffs' practice not to pay claims that are not medically necessary or reasonably required. However, Plaintiffs would not have known whether a prescriber had made an informed judgment that a particular claim for opioids was medically necessary or reasonably required, or conversely had acted under the influence of Defendants' fraudulent and deceptive marketing. It is not clear from the face of a claim whether: (1) the patient suffered from cancer or another terminal condition, for example, where long-term prescribing was medically necessary or appropriate; or (2) the prescriber was exposed to Defendants' marketing materials, treatment guidelines, or education programs, or visited by a drug representative who engaged in affirmative misrepresentations or omissions, for example.

ii. *Plaintiffs' Increased Costs Correlate with Defendants' Promotion*

464. Plaintiffs' spending in connection with opioids rose along with Defendants' spending to promote opioids. That spending was directly impacted by opioid use (and its consequences in abuse, addiction, and overdose) in Plaintiffs' geographic area.

465. It is also distressing (and a sign of further problems ahead) that the drop in opioid prescribing beginning in 2014 has been accompanied by a corresponding increase in Defendants' promotional spending, which is headed towards a new high, despite evidence of the grave toll that opioids are taking on law enforcement, public health, and individual lives.

2. Defendants' Fraudulent and Deceptive Marketing of Opioids Directly Caused Harm to Consumers in Plaintiffs' Geographic Area.

a. <u>Increased Opioid Use Has Led to an Increase in Opioid Abuse, Addiction, and Death</u>

466. Nationally, the sharp increase in opioid use has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death. Scientific evidence demonstrates a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and opioid abuse. "Deaths from opioid overdose have risen steadily since 1990 in parallel with increasing prescription of these drugs."[116] Prescription opioid use contributed to 16,917 overdose deaths nationally in 2011—more than twice as many deaths as heroin and cocaine combined; drug poisonings now exceed motor vehicle accidents as a cause of death. More Americans have died from opioid overdoses than from participation in the Vietnam War.

467. Contrary to Defendants' misrepresentations, most of the illicit use stems from *prescribed* opioids; in 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet. According to the CDC, the 80% of opioid patients who take low-dose opioids from a single prescriber (in other words, who are not illicit users or "doctor-shoppers") account for 20% of all prescription drug overdoses.

468. Death statistics represent only the tip of the iceberg. According to 2009 data, for every overdose death that year, there were nine abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 non-medical users. Nationally, there were more than 488,000 emergency room admissions for opioids other than heroin in 2008 (up from almost 173,000 in 2004).

469. Emergency room visits tied to opioid use likewise have sharply increased in Plaintiffs' geographic area.

470. Widespread opioid use and abuse in Plaintiffs' geographic area are problems even when they do not result in injury or death. Opioid addiction is affecting residents of all ages,

[116] Deborah Grady et al., *Opioids for Chronic Pain*, 171(16) Arch. Intern. Med. 1426 (2011).

ethnicities, and socio-economic backgrounds Plaintiffs' geographic area. Many addicts start with a legal opioid prescription—chronic back pain, fibromyalgia, or even dental pain—and do not realize they are addicted until they cannot stop taking the drugs.

471. These glaring omissions, described consistently by counselors and patients, mirror and confirm Defendants' drug representatives' own widespread practice, as described above, of omitting any discussion of addiction from their sales presentations to physicians or in their "educational" materials.

b. Increased Opioid Use Has Increased Costs Related to Addiction Treatment

472. Plaintiffs have opioid treatment programs within their geographic areas, Substance Alternative Clinics, that provide a comprehensive treatment program for persons addicted to heroin or other opioids.

473. In addition to intense counseling, many treatment programs prescribe additional drugs to treat opioid addiction. Nationally, in 2012, nearly 8 billion prescriptions of the two drugs commonly used to treat opioid addiction—buprenorphine/naloxone and naltrexone—were written and paid for. Studies estimate the total medical and prescription costs of opioid addiction and diversion to public and private healthcare payors to be $72.5 billion.

c. Increased Opioid Use Has Fueled An Illegal Secondary Market for Narcotics and the Criminals Who Support It

474. Defendants' success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme supplies both ends of the secondary market for opioids—producing both the inventory of narcotics to sell and the addicts to buy them. One researcher who has closely studied the public health consequences of opioids has found, not surprisingly, that a "substantial increase in the nonmedical use of opioids is a predictable adverse

effect of substantial increases in the extent of prescriptive use."[117] It has been estimated that the majority of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

475. A significant black market in prescription opioids also has arisen, not only creating and supplying additional addicts, but fueling other criminal activities.

476. In addition, because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. Self-reported heroin use nearly doubled between 2007 and 2012, from 373,000 to 669,000 individuals. In 2010, more than 3,000 people in the U.S. died from heroin overdoses, also nearly double the rate in 2006. Nearly 80% of those who used heroin in the past year had previously abused prescription opioids. Patients become addicted to opioids and then move on to heroin because these prescription drugs are roughly four times more expensive than heroin on the street. In the words of one federal DEA official, "Who would have ever thought in this country it would be cheaper to buy heroin than pills . . . [t]hat is the reality we're facing."[118]

477. That reality holds true in Plaintiffs' geographic area. According to addiction programs, a typical course sees addicts requesting more and more opioids from their doctors, who eventually cut them off. Many addicts then doctor-shop for additional prescriptions, and when that source runs out, turn to the streets to buy opioids illicitly. A significant number become heroin addicts. Addiction treatment programs, whose patient populations vary, reported rates of patients who had switched from prescription opioids to heroin ranging from half to 95%. Those addicts who do reach treatment centers often do so when their health, jobs, families and relationships reach the breaking point, or after turning to criminal activity such as prostitution and theft to sustain their

[117] G. Caleb Alexander et al., *Rethinking Opioid Prescribing to Protect Patient Safety and Public Health*, 308(18) JAMA 1865 (2012).
[118] Matt Pearce & Tina Susman, *Philip Seymour Hoffman's death calls attention to rise in heroin use*, L.A. Times, Feb. 3, 2014, http://articles.latimes.com/2014/feb/03/nation/la-na-heroin-surge-20140204 (accessed May 30, 2017).

addiction. Unfortunately, few are successful in getting and staying clean; repeated relapse is common.

3. Defendants' Fraudulent Marketing Has Led to Record Profits.

478. While the use of opioids has taken an enormous toll on Plaintiffs and residents, Defendants have gained blockbuster profits. In 2012, health care providers wrote 259 million prescriptions for opioid painkillers nationally[119]—roughly one prescription per American adult. Opioids generated $8 billion in revenue for drug companies just in 2010.

479. Financial information—where available—indicates that Defendants each experienced a material increase in sales, revenue, and profits from the fraudulent, misleading, and unfair market activities laid out above.

4. Defendants Fraudulently Concealed Their Misrepresentations

480. At all times relevant to this Complaint, Defendants took steps to avoid detection of, and fraudulently conceal, their deceptive marketing and conspiratorial behavior.

481. First, and most prominently, Defendants disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through patient advocacy and professional front organizations and KOLs. Defendants purposefully hid behind these individuals and organizations to avoid regulatory scrutiny and to prevent doctors and the public from discounting their messages.

482. While Defendants were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and exerting final approval over their content. Defendants exerted their considerable influence on these promotional and "educational" materials.

[119] Press Release, Center for Disease Control, Opioid painkiller prescribing varies widely among states: Where you live makes a difference (July 1, 2014), https://www.cdc.gov/media/releases/2014/p0701-opioid-painkiller.html (accessed May 30, 2017).

483. In addition to hiding their own role in generating the deceptive content, Defendants manipulated their promotional materials and the scientific literature to make it appear as if they were accurate, truthful, and supported by substantial scientific evidence. Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions they did not actually support. The true lack of support for Defendants' deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions, nor could they have been detected by Plaintiffs.

484. Thus, while the opioid epidemic was evident, Defendants, in furtherance of their respective marketing strategies, intentionally concealed their own role in causing it. Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the existence of claims that Plaintiffs now assert. Plaintiffs were not alerted to the existence and scope of Defendants industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

485. Through their public statements, marketing, and advertising, Defendants' deceptions deprived Plaintiffs of actual or presumptive knowledge of facts sufficient to put them on notice of potential claims.

G. Defendants Entered into and Engaged in a Civil Conspiracy

486. Defendants entered into a conspiracy to engage in the wrongful conduct complained of herein and intended to benefit both independently and jointly from their conspiratorial enterprise.

487. Each of the Defendants either actively participated and/or aided and abetted in the pursuance of this common purpose. Each of the participants in the opioid promotion enterprise described herein received substantial revenue from the scheme, in the form of sales for Manufacturer Defendants, sales and kickbacks for Distributor Defendants and Pharmacy

Defendants who reached particular monthly goals, and rebates or other financial incentives for PBM Defendants who placed opioids in a preferred place on a formulary or otherwise made opioids available for improper use—all in an effort to maximize profits.

488. Defendants reached an agreement between themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, and others through misrepresentations or omissions regarding the appropriate uses, risks and safety of opioids.

489. At all relevant times, each Defendants was aware of the enterprise's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct in the form of increased sales, distributions, and prescriptions of opioids. In fact, Distributor and Pharmacy Defendants received kickbacks from Manufacturer Defendants if they reached particular monthly goals and PBM Defendants received rebates and other financial incentives to promote the Manufacturer Defendants' drugs to ensure they were widely sold.

490. This network is interconnected, interrelated and relied upon Defendants' collective use of and reliance upon unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups. These materials were developed and funded collectively by Defendants, and Defendants relied upon the materials to intentionally mislead consumers and medical providers of the appropriate uses, risks and safety of opioids.

491. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, Defendants committed overt acts in furtherance of their conspiracy.

H. Pharmacy Defendants Flooded the Market.

492. The Pharmacies earned enormous profits by flooding the country with prescription opioids.

493. The Pharmacies are all engaged in the business of selling opioids at retail locations. The failure of the Pharmacies to effectively monitor and report suspicious orders of prescription opioids at the retail level and to implement measures to prevent diversion through improper prescriptions greatly contributed to the vast increase in opioid overdose and addiction.

494. The Pharmacies' conduct directly caused a public health and law-enforcement crisis across this country, including in Plaintiffs' geographic area.

495. Each of the Pharmacies do substantial business throughout the United States. This business includes the distribution and retail sales of prescription opioids.

496. The Pharmacies distributed and sold at retail substantial quantities of prescription opioids, including fentanyl, hydrocodone, and oxycodone in Plaintiffs' geographic area. In addition, they distributed and sold at retail substantial quantities of prescription opioids in other states, and these drugs were diverted from these other states to Plaintiffs' geographic area. The Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it and contributed substantially to the diversion problem.

497. Each participant in the supply chain of opioid distribution, including the Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring, and reporting suspicious activity.

498. As sellers of substances known to be dangerous and addictive, the Pharmacies owe a common law duty to act with care in selling at retail these dangerous drugs. In particular, because the risks to public health of uncontrolled distribution of these substances are well-known, the Pharmacies are obliged to use reasonable care to prevent diversion of dangerous drugs.

499. Defendants' common-law duties parallel their obligations under state and federal law, which inform, and provide the standard of care for, these common law duties.

500. The Pharmacies, like manufacturers and wholesale distributors, are registrants under the federal Controlled Substances Act ("CSA"). 21 C.F.R. § 1301.11. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." See 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

501. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

502. Suspicious pharmacy orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

503. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing

different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

504. Suspicious pharmacy orders are red flags for if not direct evidence of diversion.

505. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the Pharmacies themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

506. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

507. Despite their legal obligations under the common law (and under the CSA), the Pharmacies failed to meet their obligations and allowed widespread diversion to occur—and they did so knowingly.

508. The Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

509. The Pharmacies also failed to adequately use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

510. The Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

511. The Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

512. The Pharmacies were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

513. The Pharmacies were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and retail sellers. Yet, instead of taking any meaningful action to stem the flow of opioids into communities and prevent diversion, they continued to participate in the oversupply and profit from it.

514. The Pharmacies developed and maintained extensive data on opioids they distributed and sold in their retail stores. Through this data, Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country, and in Plaintiffs' geographic area. They used the data to evaluate their own sales activities and workforce. The Pharmacies also provided other defendants with data regarding, inter alia, individual doctors in exchange for rebates or other forms of

consideration. The Pharmacies' data is a valuable resource that they could have used to help stop diversion but failed to do so.

515. Performance metrics and prescription quotas adopted by the Pharmacies for their retail stores contributed to their failure to perform their duties.

516. The performance metric systems rate the pharmacist employees at the stores operated by Pharmacies based solely on productivity. These requirements place significant and unrealistic time pressures on the pharmacists.

517. The Pharmacies measure how many and how quickly prescriptions are filled daily based on store volume. Many of the Pharmacies' locations require pharmacists to fill one prescription every three minutes. The programs may also measure how many telephone calls are made to customers to refill and/or pick up prescriptions; how many flu shots are given; as well as other pharmacy tasks. All measurements focus on productivity with the end goal of maximizing retail Defendants' profits.

518. In addition to the pharmacist's other duties, Pharmacies required their employee pharmacists to fill more than 600 prescriptions per work shift.

519. At the same time that Pharmacies increased demands for productivity, they cut the hours of pharmacy technicians, leaving pharmacists severely understaffed and unable to provide all necessary services.

520. Pharmacies' high-volume and increased-profits business model led to a greater number of errors in dispensing prescriptions, which can result in substantial harm to pharmacy customers.

521. A survey conducted by the Institute for Safe Medication Practices ("ISMP") of 673 pharmacists revealed that 83% believed that distractions due to performance metrics or measured

wait times contributed to dispensing errors, and that 49% felt specific time measurements were a significant contributing factor.

522. Further, the National Association of Boards of Pharmacy found that performance metrics, which measure the speed and efficiency of prescription workflow—using such parameters as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and number of immunizations given per pharmacist shift—may distract pharmacists and impair professional judgment.

523. The practices of applying performance metrics or quotas to pharmacists in the practice of pharmacy may cause distractions that could potentially decrease pharmacists' ability to perform drug utilization review, interact with patients, and maintain attention to detail, which could ultimately lead to unsafe conditions at a pharmacy.

524. The Pharmacies' productivity policies are directly at odds with their performance of due diligence obligations required to be performed in conjunction with federal and state law, especially given the higher duty of care associated with the prescription of narcotic opioids.

525. The Pharmacies were negligent in failing to ensure, or even permit, pharmacists in their stores to exercise the reasonable care necessary under the circumstances to detect and prevent diversion.

526. The Pharmacies failed to adequately train their pharmacists and pharmacy techs on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phone, false, forged, or otherwise illegal.

527. The Pharmacies failed to instruct their pharmacists and pharmacy techs on how to address situations in which they are forced to decline filling a prescription for a customer who submitted a prescription which a pharmacist has identified as suspicious.

528. The Pharmacies have failed to train their pharmacists and pharmacy techs on how to properly exercise their judgment with respect to determinations about whether a prescription is one that should be filled, or whether, under the law, the pharmacists should refuse to fill it.

529. The Pharmacies failed to adequately use data available to them to identify doctors that were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids.

530. The Pharmacies failed to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that contributed to the opioid crisis. The Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

531. The Pharmacies failed to conduct internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly.

532. The Pharmacies failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

533. The Pharmacies violated the Controlled Substances Act by failing to have in place policies and procedures to avoid the diversion of opioids.

534. The Pharmacies failed to speak with prescribing physicians prior to dispensing opioids.

535. The Pharmacies failed to take steps such as investigating whether a prescription was written within a prescriber's scope of practice.

536. The Pharmacies failed to investigate whether an opioid prescription was appropriate for the diagnosis.

537. The Pharmacies failed to investigate whether a therapeutic regimen is within the standard of care.

538. The Pharmacies failed to investigate and consider the length of an opioid prescription prior to dispensing.

539. The Pharmacies failed to review State Prescription Drug Monitoring databases prior to dispensing.

540. The Pharmacies failed to abide by internal company policies in the dispensing of opioids.

541. The Pharmacies have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. Based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the Pharmacies.

542. Numerous state and federal drug diversion prosecutions have occurred in which prescription opioid pills were procured from Pharmacies. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

543. The litany of state and federal actions against the Pharmacies demonstrate that they routinely, and as a matter of standard operation procedure, violated their legal obligations that govern the distribution and dispensing of prescription opioids.

544. Throughout the country and in Plaintiffs' geographic area in particular, the Pharmacies were or should have been aware of numerous red flags of potential suspicious activity and diversion.

545. From the vantage point of their retail pharmacy operations, the Pharmacies knew or reasonably should have known about the disproportionate flow of opioids into Plaintiffs' geographic area and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for if not direct evidence of illicit supply and diversion. Additional information was provided by news reports, and state and federal regulatory actions, including prosecutions of pill mills in the area.

546. The Pharmacies knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in Plaintiffs' community.

547. Because of (among other sources of information) regulatory and other actions taken against the Pharmacies directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the Pharmacies were well aware that their distribution and dispensing activities fell far short of legal requirements.

548. The Pharmacies' actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent, the diversion of opioids.

549. The Pharmacies' failure to control the supply chain and prevent diversion adversely affected communities throughout the United States. Once diverted opioids do not stay put. Rather, diverted opioids move from areas of high supply to areas of high demand, traveling across state lines in a variety of ways.

550. First, prescriptions written in one state may, under some circumstances, be filled in a different state. But even more significantly, individuals transported opioids from one jurisdiction specifically to sell them in another. When authorities in some states cracked down on opioid suppliers, suppliers in other states filled the gaps. Florida in particular assumed a prominent role, as its lack of regulatory oversight created fertile ground for pill mills. Residents of other states would simply drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The practice became so common that authorities dubbed these individuals "prescription tourists."

551. Thus, once diverted into the illegal market in one location, prescription opioids could then flow freely into Plaintiffs' geographic area and elsewhere. In particular, the I-95 corridor was one route by which diverted prescription opioids travelled from Florida northward to other states.

552. For this reason, the Pharmacies' negligence in failing to prevent in diversion in Florida, and throughout the United States, substantially contributed to the opioid crisis in Plaintiffs' geographic area.

I. PBMs Ensured that Opioids Were Regularly Prescribed and Flooded the Market.

553. PBMs are brokers between payers (representing patients), drug manufacturers, and retailers and they influence which drug products are used most frequently and set prices for pharmacies.

554. The big three PBMs manage the drug benefits for nearly 95% of the population.[120] They control what drugs are covered by virtually all health insurance providers for over 260 million people. PBMs made almost $260 billion last year.[121] In 2015 they covered most of the 4 billion retail prescriptions that were covered in the United States.[122] They are key participants and play a crucial role in the administration of prescription drugs.[123]

555. PBM influence is notable especially considering the lack of competition in the PBM space. Market concentration is an important indicator of a company's ability to earn extraordinary returns, and several segments in the United States pharmaceutical distribution system are highly concentrated.[124]

556. With this kind of monopolistic structure, the top three PBMs have almost exclusive control over the dissemination of opioids. In concert with drug manufacturers who give them rebates as an incentive,[125] they choose which drugs will be on a health insurance company's formulary, thus determining which drugs will be covered. If an insurance plan does not cover a drug, that drug will not enter the marketplace to be abused.

557. People with chronic pain are at the mercy of PBMs, yet PBMs make it more difficult to get pain medication that is less addictive and easier to get opioids, because opioids are generally cheaper than non-opioid alternatives. According to a study by the New York Times and

[120] Brittany Hoffman-Eubanks, The Role of Pharmacy Benefit Managers in American Health Care: Pharmacy Concerns and Perspectives: Part 1, PHARMACY TIMES, Nov. 14, 2017, http://www.pharmacytimes.com/news/the-role-ofpharmacy-benefit-mangers-in-american-health-care-pharmacy-concerns-and-perspectives-part-1
[121] John Breslin, Health care experts call for more transparency into PBMs, PATIENTDAILY, Dec. 20, 2017, https://patientdaily.com/stories/511298841-health-care-experts-call-for-more-transparency-into-pbms
[122] Lydia Ramsey and Skye Gould, A huge pharma middleman just lost its biggest customer — and it shows how drug pricing really works, BUSINESS INSIDER, Apr. 25, 2017, http://www.businessinsider.com/express-scripts-esrx-anthemnot-renewing-pbm-2017-4
[123] Health Policy Brief, supra note 33.
[124] Neeraj Sood, Tiffany Shih, Karen Van Nuys, Dana Goldman, Follow the Money: The Flow of Funds In the Pharmaceutical Distribution System, HEALTH AFFAIRs, Jun. 13, 2017, https://www.healthaffairs.org/do/10.1377/hblog20170613.060557/full/
[125] Health Policy Brief, supra note 33.

ProPublica of 35.7 million people on Medicare prescription drug plans, in the second quarter of 2017 only one-third of them had access to pain medication less addictive than opioids.[126]

558. The Manufacturer and PBM Defendants and their co-conspirators engaged in a conspiracy to increase the use of the least expensive, most addictive opioid by controlling the drugs' placement on the formulary. The PBM formularies are a critical piece of the enterprise described herein. The enterprise would not have succeeded absent the opioids' placement on the formulary. The formulary controlled which opioids were paid for, reimbursed, and covered by public and private pharmacy benefit plans.

559. The PBM and Manufacturer Defendants coordinated to ensure that the PBM Defendants got the maximum profit at the expense of patients.

560. Even when they were asked to limit accessibility to opioids, PBMs refused. The seeds of the opioid epidemic were sown with early overprescription of OxyContin. In 2001, when officials in the West Virginia state employee health plan tried to get Purdue, which manufactured OxyContin, to require pre-authorization, Purdue refused.[127] Using the financial quid pro quo it had with the state's PBM, it paid Merck Medco (now Express Scripts) to prevent insurers from limiting access to the drug:

> The strategy to pay Merck Medco extended to other big pharmacy benefit managers and to many other states, according to a former Purdue official responsible for ensuring favorable treatment for OxyContin. The payments were in the form of "rebates" paid by Purdue to the companies. In return, the pharmacy benefit managers agreed to make the drug available without prior authorization and with low copayments.
>
> "That was a national contract," Bernadette Katsur, the former Purdue official, who negotiated contracts with pharmacy benefit managers, said in an interview. "We would negotiate a certain rebate percentage for keeping it on a certain tier related to copay or

[126] Thomas and Ornstein, supra note 45.
[127] David Armstrong, Drug maker thwarted plan to limit OxyContin prescriptions at dawn of opioid epidemic, STAT, Oct. 26, 2016, https://www.statnews.com/2016/10/26/oxycontin-maker-thwarted-limits/

> whether it has prior authorization. We like to keep prior authorization off of any drug."[128]

561. PBMs are "driving patients to opioids, away from abuse-deterrent form (ADF) and less addictive forms of opiates through formulary and pricing strategies."[129]

562. Not only do PBMs place roadblocks in the way of limiting excessive opioid prescriptions, but they also make it more difficult to obtain Abuse Deterrent Formula (ADF) opioids. These pills are more difficult to physically alter (crushing to snort or dissolving to inject) and therefore are less prone to abuse.[130] The three major PBMs carry at most 3 of the 10 FDA approved ADF opioids.[131] A study by Tufts CSSD found that ninety-six percent (96%) of all prescription opioids were non-ADF in 2015.[132]

563. This denial was endorsed by the Institute for Clinical and Economic Review, a private organization funded in part by some of the largest health plans and PBMs, that claimed that ADF opioids provided neither financial or societal benefits, even though they were given data showing that ADF OxyContin could prevent 4,300 cases of abuse and save $300 million over a five-year period.[133]

> ICER ignored research that demonstrated abuse deterrent Oxy reduced abuse by 20 percent and reduced the average daily dose of OxyContin from 80mg to 60mg. Perhaps even more important, it reduced sharing and selling of the drug for getting high ("diversion") by nearly 90 percent. The diversion of generic painkillers is responsible for as many as 63 percent of fatal

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[128] *Id*.
[129] Charles L. Bennett MD PhD MPP, Do you have pain, cancer, or diabetes? Your PBM may now be your doctor for these illnesses, COLLABRX, Dec. 27, 2017, http://www.collabrx.com/pain-cancer-diabetes-pbm-may-now-doctorillnesses/
[130] Peter J. Pitts, Pharmacy benefit managers are driving the opioid epidemic, SW NEWS MEDIA, Nov. 21, 2017, http://www.swnewsmedia.com/shakopee_valley_news/news/opinion/guest_columns/pharmacy-benefit-managersare-driving-the-opioid-epidemic/article_2f6be2a1-c7a3-5f8d-9f3e-, 61d29d25c84b.html
[131] Charles L. Bennett MD PhD MPP, Do you have pain, cancer, or diabetes? Your PBM may now be your doctor for these illnesses, COLLABRX, Dec. 27, 2017, http://www.collabrx.com/pain-cancer-diabetes-pbm-may-now-doctorillnesses/
[132] Pitts, supra note 214.
[133] Robert Goldberg & Peter Pitts, ICER Perpetuates the Opioid Crisis, Morning Consult, MORNING CONSULT, May 11, 2017, https://morningconsult.com/opinions/icer-perpetuates-opioid-crisis/

> prescription drug overdoses. ICER consciously decided to ignore the human cost of this deadly behavior.
>
> What the ICER report ignores entirely is that one of the factors driving abuse and addiction is the inappropriate use of generic opioids for conditions that have non-opioid, on-label options. Fifty-two percent of patients diagnosed with osteoarthritis receive an opioid pain medicine as first-line treatment, as do 43 percent of patients diagnosed with fibromyalgia and 42 percent of patients with diabetic peripheral neuropathy.[134]

564. What is inconceivable is that PBMs, while making it easy to obtain generic highly addictive opioids, make it harder to obtain treatment. The NY Times/ProPublica study found that insurers have erected more hurdles to approving addiction treatments than for the addictive substances themselves.[135] Only after being subject to much public pressure and congressional investigations did some insurers remove the barriers to addiction treatment.

565. A 2008 study by the Mayo Clinic[136] found that patients who were weaned off opioids and followed a non-drug treatment experienced less pain than when they were on opioids and had improved functioning. Some plans cover these costs but other do not.[137]

566. PBM Defendants fraudulently hid their financial relationship with Manufacturer, Distributor, and Pharmacy Defendants, making it impossible for Plaintiffs to discover the PBM Defendants' role in promoting opioids through reasonable diligence.

567. The Manufacturer Defendants knowingly and intentionally financially incentivized the PBM Defendants to place their opioids on the PBMs formularies irrespective of medical necessity, resulting in widespread and unnecessary overuse.

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[134] Id.
[135] Thomas and Ornstein, supra note 45.
[136] Available at https://www.ncbi.nlm.nih.gov/pubmed/18804915
[137] Barry Meier and Abby Goodnough, New Ways To Treat Pain Meet Resistance, THE NEW YORK TIMES, Jun. 22, 2016, https://www.nytimes.com/2016/06/23/business/new-ways-to-treat-pain-without-opioids-meet-resistance.html ?mcubz=1.

568. The PBM Defendants knowingly and intentionally chose to include opioids on their formularies that were more addictive to users because they generated greater profits. This failure led directly to the increased likelihood of addiction.

569. The PBM Defendants knowingly and intentionally chose to include opioids that were easier to misuse (for example, by crushing them into powder and mixing them with liquid in order to inject them) instead of Abuse Deterrent Formulations ("ADFs") which tended to be more expensive. This choice directly led to the ease with which the pills could be misused.

570. The PBM Defendants knowingly and intentionally made it more expensive or more difficult to obtain knowingly efficacious non-opioid medications for pain. This led directly to the increased sale and use of opioids.

571. The PBM Defendants knowingly and intentionally chose not to include certain medications that would prevent overdoses or made them more difficult or expensive to obtain.

572. The PBM Defendants chose not to cover or provide less coverage for drug treatment.

573. The PBM Defendants knowingly and intentionally created their formularies to ensure that an excessive number of pills were made available to users for use and abuse.

574. The PBM Defendants made deceptive representations about using opioids to treat chronic pain and/or omitting or concealing material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each PBM Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

575. The efforts to artificially increase the number of opioids prescriptions implemented by PBMs, directly and predictably caused a corresponding increase in opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and

has increased in parallel with [opioid] overdoses."[138] Many abusers start with legitimate prescriptions. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "[t]o reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[139] The PBMs' role in increasing prescriptions played an enormous role in the current opioid epidemic.

576. The PBM Defendants also had the power to shut off the supply of illicit opioids into Plaintiffs' geographic area.

577. The PBM Defendants had the power to minimize the sale and use of less effective, more addictive and more divertible opioids. They could have prohibited doctors from prescribing opioids for non-chronic pain when other non-opioid options were available. They could have responded favorably to direct requests from governmental payors attempting to control opioid flow. They could have made it easier for patients to access less addictive, less dangerous drugs.

578. There are steps the PBMs could take. They could make it easier to access other nonaddictive forms of pain relief. They could require doctors to start treating pain first with non-opioid pain medications as recommended by the CDC and turn to opioids as a last resort. They could cover alternative, non-medication treatments for pain. They could make addiction treatment more accessible. They could make their pricing more transparent so everyone could see if they were being improperly influenced by manufacturers to make choices for financial, not medical, reasons. No single actor is to blame for this epidemic, but PBMs have a unique role to play.

[138] 3 Rose A Rudd, et al., Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014, MORBIDITY AND MORTALITY WKLY REP., Jan. 1, 2016, https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm (emphasis added)
[139] *Id.*

J. Defendants Flooded Plaintiffs' Geographic Area with Suspiciously Large Amounts of Opioids.

579. The Distributor and Pharmacy Defendants are opioid distributors in Plaintiffs' geographic area.

580. The Distributor and Pharmacy Defendants purchased opioids from manufacturers, such as the named defendants herein, and sold them to pharmacies throughout Plaintiffs' geographic area.

581. The Distributor and Pharmacy Defendants played an integral role in the chain of opioids being distributed throughout Plaintiffs' geographic area.

582. The Defendants were each on notice that the controlled substances they manufactured and distributed were the kinds that were susceptible to diversion for illegal purposes, abused, overused, and otherwise sought for illegal, unhealthy, and problematic purposes.

583. The Defendants were each on notice that there was an alarming and suspicious rise in manufacturing and distributing opioids to retailers within the Plaintiffs' geographic area during this time period.

584. As entities involved in the manufacture and distribution of opioid medications, Defendants were engaged in abnormally and/or inherently dangerous activity and had a duty of care under State and Federal Law.

585. The Defendants had a duty to notice suspicious or alarming orders of opioid pharmaceuticals and to report suspicious orders to the proper authorities and governing bodies including the DEA and State agencies.

586. The Defendants knew or should have known that they were supplying vast amounts of dangerous drugs to Plaintiffs that were already facing abuse, diversion, misuse, and other problems associated with the opioid epidemic.

587. The Defendants failed in their duty to take any action to prevent or reduce the distribution of these drugs.

588. The Defendants were in a unique position and had a duty to inspect, report, or otherwise limit the manufacture and flow of these drugs to Plaintiffs.

589. The Defendants, in the interest of their own massive profits, intentionally failed in this duty.

590. The Defendants have displayed a continuing pattern of failing to submit suspicious order reports.

591. Despite the charges, fines, and penalties brought against the Distributor and Pharmacy Defendants in the past, they continued to fail to report suspicious orders or prevent the flow of prescription opioids, including into Plaintiffs' geographic area.

592. The Healthcare Distribution Management Association ("HDMA") created "Industry Compliance Guidelines" which stressed the critical role of each member of the supply chain in distributing controlled substances. The HDMA guidelines provided that "[a]t the center of a sophisticated supply chain, Distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

593. Between the years in question, including 2006 through 2016, the Distributor and Pharmacy Defendants have shipped millions of doses of highly addictive controlled opioid pain killers into Plaintiffs' geographic area.

594. Many of these orders should have been stopped, or at the very least, investigated as potential suspicious orders.

595. The sheer volume of the increase in opioid pain medications, including OxyCodone, being distributed to retailers, should have put the Defendants on notice to investigate and report such orders.

596. The Defendants manufactured and delivered an excessive and unreasonable amount of opioid pain medications to retailers in Plaintiffs' geographic area.

597. Upon information and belief, the Defendants did not refuse to manufacture, ship, or supply any opioid medications to any pharmacy in Plaintiffs' geographic area from 2006 to the present.

598. The Defendants knew or should have known that they were manufacturing and distributing levels of opioid medications that far exceeded the legitimate needs of Plaintiffs.

599. The Defendants also paid their sales force bonuses and commissions on the sale of most or all of the highly addictive opioid pain medications within Plaintiffs' geographic area.

600. The Defendants made substantial profits from the opioids sold in Plaintiffs' geographic area.

601. The Defendants violated State and Federal rules and regulations for manufacturers and distributors, including the aforementioned section 80.22, by failing to properly report suspicious orders.

602. By the actions and inactions described above, the Defendants showed a reckless disregard for the safety of the residents of Plaintiffs.

603. By the actions and inactions described above, the Defendants caused great harm to Plaintiffs.

604. On December 27, 2007, the U.S. Department of Justice, Drug Enforcement Administration, sent a letter to Defendants stating, "This letter is being sent to every entity in the United States registered with the Drug Enforcement Agency (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 C.F.R. § 1301.74(b)."

605. The DEA has provided briefings to each of the Defendants and conducted a variety of conferences regarding their duties under federal law.

606. The DEA sent a letter to each of the Defendants on September 26, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

607. The DEA sent a second letter to each of the Defendants on December 27, 2007. This letter reminded the Defendant Distributors of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The letter further explains:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.
>
> The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on

> the patterns of the registrant's customer base and the pattern throughout the segment of the regulated industry.
>
> Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.
>
> When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."
>
> Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 U.S.C. §§ 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

608. As a result of the decade-long refusal by the Defendants to abide by federal law, the DEA has repeatedly taken administrative action to force compliance. The United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 177 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders. The Drug Enforcement Administration's Adjudication of Registrant Actions, United States Department of Justice, Office

of the Inspector General, Evaluation and Inspections Divisions, I-2014-003 (May 2014). The public record reveals many of these actions.

609. Rather than abide by these public safety statutes, the Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[140]

FIRST CAUSE OF ACTION
PUBLIC NUISANCE
(AGAINST ALL DEFENDANTS)

610. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

611. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or omissions which endanger or injure the property, health, safety or comfort of a considerable number of persons in Plaintiffs' geographic area by their production, promotion, and marketing of opioids for use by residents of Plaintiffs.

[140] *See* Lenny Bernstein and Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, WASH. POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic- grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.d84d374ef062; Lenny Bernstein and Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, WASH. POST (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea- enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.b44410552cde.

612. Defendants' conduct and subsequent sale of its opioid products is not only unlawful, but has also resulted in substantial and unreasonable interference with the public health.

613. Defendants' conduct is not insubstantial or fleeting. Indeed, Defendants' unlawful conduct has so severely impacted public health on every geographic and demographic level that the public nuisance perpetrated by Defendants' conduct is commonly referred to as a "crisis" or an "epidemic." It has caused deaths, serious injuries, and a severe disruption of public peace, order and safety; it is ongoing, and it is producing permanent and long-lasting damage.

614. Each of the Defendants subverted the public order, decency, and morals of, and caused inconvenience and damage to, Plaintiffs and their residents by, among other things, promoting and marketing the use of opioids for indications not federally approved, circulating false and misleading information concerning their safety and efficacy and/or downplaying or omitting the risk of addiction arising from their use in violation of the FDUTPA. In so doing, the Defendants acted unreasonably and with actual malice.

615. Defendants subverted the public order, decency, and morals of, and caused inconvenience and damage to, Plaintiffs by failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances, by filling those suspicious orders and by failing to report suspicious orders of opioids as required by law. In so doing, the Manufacturing Defendants, Distributor Defendants, PBM Defendants, and Pharmacy Defendants acted unreasonably and with actual malice. There is no legitimate societal interest in the PBM Defendants promoting and reimbursing for pills that are more addictive and easier to divert purely for financial reasons by giving such drugs prime position on their formularies.

616. As detailed herein, Defendants' conduct has interfered, and continues to interfere, with rights common to the general public of Plaintiffs and has caused Plaintiffs to sustain damages special and particular, of a kind not sustained by the general public, including, but not limited to,

increased healthcare expenditures, law enforcement and judicial expenditures, increased prison and public works expenditures, increased substance abuse treatment and diversion plan expenditures, increased emergency and medical care services and autopsies, the costs of processing and paying for fraudulent prescriptions and lost economic opportunity.

617. Defendants' conduct constitutes a public nuisance.

618. Defendants' conduct directly and proximately caused injury to Plaintiffs and their residents.

619. Plaintiffs have been injured by reason of Defendants' creation of the public nuisance.

620. Plaintiffs are entitled to recover their damages caused by Defendants' creation of this public nuisance in an amount to be determined at trial, plus costs and attorneys' fees.

WHEREFORE, Plaintiffs demand judgment against defendants, awarding Plaintiffs compensatory damages in an amount sufficient to fairly and completely compensate Plaintiffs for all damages, penalties, and costs, attorneys' fees as authorized by statute or rule; interest, costs and disbursements; and such further relief, including injunctive relief, as this Court may deem just and proper.

SECOND CAUSE OF ACTION

NEGLIGENCE PER SE
(AGAINST ALL DEFENDANTS)

621. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

622. Defendants have a duty to comply with the regulations of the Florida Drug and Cosmetic Act. (FDCA), Florida Statutes, Title XXXIII, Chapter 499, et seq.

623. Failure to comply with the FDCA constitutes negligence per se.

624. Defendants failed to comply with the FDCA.

625. In the instant case, as detailed above, the FDCA requires that the Defendants know their customers, which includes, an awareness of the customer base, knowledge of the average prescriptions filled each day, the percentage of controlled substances compared to overall purchases, a description of how the dispenser fulfills its responsibility to ensure that prescriptions filled are for legitimate medical purposes, and identification of physicians and bogus centers for the alleged treatment of pain that are the dispenser's most frequent prescribers.

626. Defendants have failed to diligently respond to the suspicious orders which Defendants have filled.

627. Defendants have failed to provide effective controls and procedures to guard against diversion of controlled substances in contravention of Florida law.

628. Defendants have willfully turned a blind eye towards the actual facts by regularly distributing large quantities of controlled substances to retailers and dispensers who are serving a customer base comprised of individuals who are themselves abusing and/or dealing prescription medications, many of whom are addicted and all of whom can reasonably be expected to become addicted.

629. Defendants negligently acted with others by dispensing controlled substances for illegitimate medical purposes, operating bogus pain clinics which do little more than provide prescriptions for controlled substances and thereby creating and continuing addictions to prescription medications in this state.

630. Defendants have, by their acts and omissions, proximately caused and substantially contributed to damages to Plaintiffs by violating Florida law, by creating conditions which contribute to the violations of Florida laws by others, and by their negligent and/or reckless disregard of the customs, standards and practices within their own industry.

631. Plaintiffs have suffered and will continue to suffer enormous damages as the proximate result of the failure by Defendants to comply with Florida law.

632. Defendants' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with the negligent and/or criminal acts of third parties.

633. Defendants are in a class of a limited number of parties that can legally sell and distribute opioids, which places it in a position of great trust by Plaintiffs

634. The trust placed in Defendants by Plaintiffs through the license to distribute opioids in Plaintiffs creates a duty on behalf of Defendants to prevent diversion of the medications it supplies to illegal purposes.

635. A negligent and/or intentional violation of this trust poses distinctive and significant dangers to Plaintiffs and residents from the diversion of opioids for non-legitimate medical purposes and addiction to the same by consumers.

636. Defendants were negligent in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent and/or ameliorate such distinctive and significant dangers.

637. Defendants are required to exercise a high degree of care and diligence to prevent injury to the public from the diversion of opioids during distribution.

638. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of its business.

639. Defendants are in exclusive control of the management of the opioids it distributed to pharmacies and drug stores in Plaintiffs' geographic area.

640. Plaintiffs are without fault and the injuries to the Counties and their residents would not have occurred in the ordinary course of events had Defendants used due care commensurate to the dangers involved in the distribution of opioids.

641. Plaintiffs are within the class of persons the FDCA was intended to protect.

642. The harm that has occurred is the type of harm that the FDCA were intended to guard against.

643. Defendants breached this duty by failing to take any action to prevent or reduce the distribution of the opioids.

644. As a direct and proximate result of Defendants' negligence per se, Plaintiffs have suffered and continues to suffer injury, including but not limited to incurring excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids, bearing the massive costs of these illnesses and conditions by having to provide necessary resources for care, treatment facilities, and law enforcement services for Plaintiffs' Residents and using Plaintiffs' resources in relation to opioid use and abuse.

645. Defendants were negligent in failing to monitor and guard against third-party misconduct and participated in and enabled such misconduct.

646. Defendants were negligent in failing to monitor against diversion of opioid pain medications.

647. Defendants' violations constitute negligence per se.

648. Plaintiffs are entitled to recover damages caused by Defendants' fraud in an amount to be determined at trial.

WHEREFORE, Plaintiffs demand judgment against defendants, awarding Plaintiffs compensatory damages in an amount sufficient to fairly and completely compensate Plaintiffs for all damages, penalties, and costs; attorneys' fees as authorized by statute or rule; interest, costs and

disbursements; and such further relief, including injunctive relief, as this Court may deem just and proper.

THIRD CAUSE OF ACTION

NEGLIGENT MARKETING
(AGAINST ALL DEFENDANTS)

649. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

650. Defendants had a duty to exercise reasonable care in the marketing of opioids.

651. Defendants were aware of the potentially dangerous situation involving opioids.

652. Defendants marketed opioids in an improper manner by:

a. overstating the benefits of chronic opioid therapy, promising improvement in patients' function and quality of life, and failing to disclose the lack of evidence supporting long-term use;

b. trivializing or obscuring opioids' serious risks and adverse outcomes, including the risk of addiction, overdose, and death;

c. overstating opioids' superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives;

d. mischaracterizing the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms;

e. marketing opioids for indications and benefits that were outside of the opioids' labels and not supported by substantial evidence.

653. It was Defendants' marketing—and not any medical breakthrough—that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic.

654. Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing materials. These KOLs and Front Groups were important elements of Defendants' marketing plans, which specifically contemplated their use, because they seemed independent and therefore outside FDA oversight. Through unbranded materials, Defendants, with their own knowledge of the risks, benefits and advantages of opioids, presented information and instructions concerning opioids generally that were contrary to, or at best, inconsistent with information and instructions listed on Defendants' branded marketing materials and drug labels. Defendants did so knowing that unbranded materials typically are not submitted to or reviewed by the FDA.

655. Defendants also marketed opioids through the following vehicles: (a) KOLs, who could be counted upon to write favorable journal articles and deliver supportive CMEs; (b) a body of biased and unsupported scientific literature; (c) treatment guidelines; (d) CMEs; (e) unbranded patient education materials; and (f) Front Group patient-advocacy and professional organizations, which exercised their influence both directly and through Defendant-controlled KOLs who served in leadership roles in those organizations.

656. Defendants knew or should have known that opioids were unreasonably dangerous and could cause addiction.

657. Defendants' marketing was a factor in physicians, patients, and others to prescribe or purchase opioids.

658. As a direct and proximate result of Defendants' negligence, Plaintiffs suffered and continues to suffer injury, including but not limited to incurring excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids, bearing the massive costs of these illnesses and conditions by having to provide necessary resources for care, treatment

facilities, and law enforcement services for Plaintiffs and using Plaintiffs' resources in relation to opioid use and abuse.

659. Plaintiffs are entitled to recover damages caused by Defendants' negligence in an amount to be determined at trial.

WHEREFORE, Plaintiffs demand judgment against defendants, individually and/or jointly and severally, awarding Plaintiffs compensatory damages in an amount sufficient to fairly and completely compensate Plaintiff for all damages, penalties, and costs; attorneys' fees as authorized by statute or rule; interest, costs and disbursements; and such further relief, including injunctive relief, as this Court may deem just and proper.

FOURTH CAUSE OF ACTION

NEGLIGENCE
(AGAINST ALL DEFENDANTS)

660. Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

661. Defendants have a duty to exercise reasonable care in the distribution, promotion, dispensing, and marketing of opioids.

662. Defendants breached this duty by failing to take any action to prevent or reduce the distribution of the opioids.

663. As a proximate result, Defendants and its agents have caused Plaintiffs to incur excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids, the County has borne the massive costs of these illnesses and conditions by having to provide necessary resources for care, treatment facilities, and law enforcement services for Plaintiffs and using Plaintiffs' resources in relation to opioid use and abuse.

664. Plaintiffs are entitled to recover damages caused by Defendants' negligence in an amount to be determined at trial.

WHEREFORE, Plaintiffs demand judgment against defendants, awarding Plaintiffs compensatory damages in an amount sufficient to fairly and completely compensate Plaintiffs for all damages, penalties and costs, attorneys' fees as authorized by statute or rule; interest, costs and disbursements; and such further relief, including injunctive relief, as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

665. Plaintiffs demand a jury by trial of all issues so triable as a matter of law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, as to the FIRST, SECOND, THIRD, and FOURTH Causes of Action, awarding Plaintiffs in amounts that exceed the jurisdiction of all lower Courts:

i. Abatement of the nuisance;

ii. Compensatory damages in an amount sufficient to fairly and completely compensate Plaintiffs for all damages;

iii. Treble damages, penalties, and costs

iv. Punitive damages;

v. Attorneys' fees;

vi. Interest, Costs and Disbursements; and

vii. Such further relief, including injunctive relief, as this Court may deem just and proper.

Dated: March 16, 2023

Respectfully submitted,

By: /s/ *Rebeca Martínez*
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